Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection		
DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.		
1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007339

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/13/2020

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007340

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961017]
2.	Birth Date:	(b) (6)/1956
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007341

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/13/2020
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007342

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007343

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation/Death	Aug/13/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007344

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sulfa allergy]
	Start Date:	UNK/UNK/1960
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allegies]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendectomy]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

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FDA-CBER-2021-5683-0007345

1.e

Line/MH Number:	[5]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
Start Date:	UNK/UNK/2003
Ongoing:	NO End Date: UNK/UNK/2003

1 f

Line/MH Number:	[6]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastrointestinal perforation]
Start Date:	UNK/UNK/2003
Ongoing:	NO End Date: UNK/UNK/2003

1.g

Line/MH Number:	[7]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SURGERY FOR SMALL VESSEL]
Start Date:	UNK/UNK/2003
Ongoing:	NO End Date: UNK/UNK/2003

1 h

Line/MH Number:	[8]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hernia]
Start Date:	UNK/UNK/2008
Ongoing:	NO End Date: UNK/UNK/2009

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007346

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hernia repair surgery]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right foot morton's]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[torn meniscus in right knee]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Knee surgery]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007347

1 m

Line/MH Number:	[13]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right tivia tear]
Start Date:	UNK/UNK/2009
Ongoing:	NO End Date: UNK/UNK/2009

1 n

Line/MH Number:	[14]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vasectomy]
Start Date:	UNK/UNK/1990
Ongoing:	NO End Date: UNK/UNK/1990

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007348

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/13/2020
2.	Weight:	[233.4]
3.	Unit:	LB
4.	Height:	[76.5]
5.	Unit:	in
6.	Body Mass Index:	[28.0]

Vital Signs Details

7.a		
	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007349

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/13/2020
2.	Randomization Number:	[228445]
3.	Randomization Group:	[ ]

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FDA-CBER-2021-5683-0007350

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DS6]
5.b	Sample ID	[BP5DS7]
5.c	Sample ID	[BP5DS8]
5.d	Sample ID	[BPRHW6]
5.e	Sample ID	[BPRHW7]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007351

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DRJ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007352

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/13/2020 17:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007353

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007354

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/1/2020
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007355

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO

2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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FDA-CBER-2021-5683-0007356

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2 h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007357

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/1/2020

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007358

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP96DD]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007359

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 10:28
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007360

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007361

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO

2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007362

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2 h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007363

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNH2]
5.b	Sample ID	[BNVTLX]
5.c	Sample ID	[BNVTLY]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007364

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007365

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNMH]
5.b	Sample ID	[BSH4KG]
5.c	Sample ID	[BSH4KH]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007366

Header Text: c4591001

Visit: V5_MONTH12_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007367

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007368

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	ERRONEOUS VISIT

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FDA-CBER-2021-5683-0007369

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Electronic Sample Tracking			
1.	Data Origin	Not Applicable	Comments
2.	Sample Type	Not Applicable	Comments
3.	Sample Collected?	Not Applicable	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable [ ]	Comments

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[ ]
5.b	Sample ID	[ ]
5.c	Sample ID	[ ]

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FDA-CBER-2021-5683-0007370

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/29/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

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FDA-CBER-2021-5683-0007371

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Signs and Symptoms		
1.	Date of Assessment:	Oct/29/2020
2.	Date of First Symptom Started:	Oct/20/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/31/2020

Symptoms		
4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4 h	Symptoms:	DIARRHEA
	Was symptom present?	NO

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007372

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[nasal congestion]

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FDA-CBER-2021-5683-0007373

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007374

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Microbiology Specimen

1.	Actual Date of Collection:	Not Done //	Comments
2.	Specimen Type:	Not Done	Comments
3.	Specimen Collection Location:	Not Done	Comments
4.	Assay Code and Description:	Not Done	Comments
5.	Device Type:	Not Done	Comments
6.	Trade Name:	Not Done	Comments
7.	Test Result:	Not Done	Comments
8.	Comments/Findings/Details:	Not Done [ ]	Comments
9.	Trade Name Other, Specify:	Not Done [ ]	Comments

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FDA-CBER-2021-5683-0007375

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[CV11242]

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FDA-CBER-2021-5683-0007376

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[home swab was collected]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

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FDA-CBER-2021-5683-0007377

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** RESPIRATORY TREATMENT
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007379

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Respiratory Treatment			
1.	What is the treatment Identifier?	Not Done [ ]	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done	Comments
3.	Treatment:	Not Done	Comments
4.	Treatment:	Not Done [ ]	Comments
5.	Start Date:	Not Done //	Comments
6.	Ongoing?	Not Done	Comments

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FDA-CBER-2021-5683-0007380

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Illness Details		
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [upper respiratory tract infection] Date of Diagnosis: Oct/22/2020
3.	Toxicity Grade:	1

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FDA-CBER-2021-5683-0007381

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Illness Details

1.	Category of Clinical Event:	Not Done	Comments
2.	Subcategory of Clinical Event:	Not Done	Comments
3.	Was a diagnosis obtained?	Not Done	Comments
4.	Toxicity Grade:	Not Done	Comments

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Form Version: 30-Jul-2020 21:27
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Done	Not Done	Not Done	Not Done		Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007384

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Lab Chemistry Details

1.	Lab Panel:	Not Done	Comments
2.	Laboratory Name and Address	Not Done [ ]	Comments
3.	Collection Date:	Not Done //	Comments
4.	Specimen Type:	Not Done	Comments

Lab Result

5.a

Sponsor ID:	Not Done [ ]	Comments
Test:	C Reactive Protein_PX329	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.b	Sponsor ID:	Not Done [ ]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Done [ ]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.d	Sponsor ID:	Not Done [ ]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.e	Sponsor ID:	Not Done [ ]	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.f

Sponsor ID:	Not Done [ ]	Comments
Test:	Blood Urea Nitrogen_PX47	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

5.g

Sponsor ID:	Not Done [ ]	Comments
Test:	Creatinine_PX48	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 30-Jul-2020 21:28
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Done	Not Done	Not Done	Not Done		Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done

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FDA-CBER-2021-5683-0007389

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Laboratory Data Hematology

1.	Lab Panel:	Not Done	Comments
2.	Laboratory Name and Address	Not Done [ ]	Comments
3.	Collection Date:	Not Done //	Comments
4.	Specimen Type:	Not Done	Comments

Lab Result

5.a	Sponsor ID:	Not Done [ ]	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.b	Sponsor ID:	Not Done [ ]	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Done [ ]	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.d

Sponsor ID:	Not Done [ ]	Comments
Test:	Platelets_PX5	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

5.e

Sponsor ID:	Not Done [ ]	Comments
Test:	Leukocytes_PX7	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.f	Sponsor ID:	Not Done [ ]	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Done [ ]	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5 h	Sponsor ID:	Not Done [ ]	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.i	Sponsor ID:	Not Done [ ]	Comments
	Test:	Basophils_PX610	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.j

Sponsor ID:	Not Done [ ]	Comments
Test:	Lymphocytes_PX611	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007395

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - COVID
Form Version: 30-Jul-2020 21:27
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	**Record Identifier:**	**Systolic:**	**Diastolic:**	Repeating Pages
		Not Done	Not Done	Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Vital Signs

1.	Date:	Not Done //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Done 1	
	Systolic:	Not Done [ ]	Comments
	Diastolic:	Not Done [ ]	Comments
	Respiratory Rate in respirations/minute:	Not Done [ ]	Comments
	Heart Rate in beats/minute:	Not Done [ ]	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007397

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Form Version: 30-Jul-2020 21:28
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details	Form Instance
1.	Not Done	Record Identifier: / Oxygen Saturation Not Done / Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007398

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History

Vital Signs

1.	Date:	Not Done //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Done 1	
	SPO2 Pulse Oximetry %	Not Done [ ]	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007399

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007400

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Oxygenation Parameters			
1.	Date Time of Assessment:	Not Done //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done [ ]	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done [ ]	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007401

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007402

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications			
1.	What is the medication identifier?	Not Done [ ]	Comments
2.	Category:	Not Done	Comments
3.	Concomitant Medications Pre-specified:	Not Done	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Done [ ]	Comments
5.	Start Date:	Not Done //	Comments
6.	Ongoing?	Not Done	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007403

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007404

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Imaging			
1.	Date of Assessment:	Not Done //	Comments
2.	Location of Assessment:	Not Done	Comments
3.	Type of Imaging Exam:	Not Done	Comments
4.	Assessment:	Not Done	Comments

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007405

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/07/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/7/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A1

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FDA-CBER-2021-5683-0007406

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/07/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BSJ600]
5.b	Sample ID	[BSJ601]
5.c	Sample ID	[BR856J]

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FDA-CBER-2021-5683-0007407

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007408

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007409

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

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FDA-CBER-2021-5683-0007410

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007411

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** DATE OF VISIT - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

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FDA-CBER-2021-5683-0007412

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007413

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Head Injury	Nov/29/2020 UNK:UNK	NO End Date Time: Dec/17/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	BROKEN SACRUM	Nov/29/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Fall	Nov/29/2020 UNK:UNK	NO End Date Time: Nov/29/2020 UNK:UNK	Repeating Pages
4. DELETED	ADVERSE EVENT	4	Fall Related Injuries	Nov/29/2020 UNK:UNK	YES	Repeating Pages
5. DELETED	ADVERSE EVENT	5	Head Injury	Nov/29/2020 UNK:UNK	YES	Repeating Pages
6. DELETED	ADVERSE EVENT	6	Broken Sacrum	Nov/29/2020 UNK:UNK	YES	Repeating Pages
7.	ADVERSE EVENT	7	Neck Pain	Nov/30/2020 UNK:UNK	YES	Repeating Pages
8.	ADVERSE EVENT	8	Right Shoulder Pain	Nov/30/2020 UNK:UNK	YES	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007414

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Head Injury]
4.	Start Date Time:	Nov/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/17/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Fall]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020473499]

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[BROKEN SACRUM]
4.	Start Date Time:	Nov/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Fall]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0007418

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall]
4.	Start Date Time:	Nov/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/29/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Fall at home]

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10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0007420

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~Fall Related Injuries~~]
4.	Start Date Time:	~~Nov/29/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~YES~~
6.	Toxicity Grade:	~~2~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~YES~~ ~~Is this serious event associated with congenital anomaly or birth defect?~~ ~~NO~~ ~~Did this serious event result in death?~~ ~~NO~~ ~~Did this serious event require or prolong hospitalization?~~ ~~YES~~ ~~Did this serious event result in persistent or significant disability/incapacity?~~ ~~NO~~ ~~Is this serious event life threatening?~~ ~~NO~~ ~~Other medically important serious event~~ ~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~

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FDA-CBER-2021-5683-0007421

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to: CONCOMITANT NON-DRUG TREATMENT~~
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~
12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~NOT RECOVERED/NOT RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0007422

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~5~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~Head Injury~~]
4.	Start Date Time:	~~Nov/29/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~YES~~
6.	Toxicity Grade:	~~2~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~YES~~ ~~Is this serious event associated with congenital anomaly or birth defect?~~ ~~NO~~ ~~Did this serious event result in death?~~ ~~NO~~ ~~Did this serious event require or prolong hospitalization?~~ ~~NO~~ ~~Did this serious event result in persistent or significant disability/incapacity?~~ ~~NO~~ ~~Is this serious event life threatening?~~ ~~NO~~ ~~Other medically important serious event~~ ~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~

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***** THIS REPEATING FORM HAS BEEN DELETED *****

9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~Fall~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~
12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~NOT RECOVERED/NOT RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[~~2020473499~~]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007424

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~6~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~Broken Sacrum~~]
4.	Start Date Time:	~~Nov/29/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~YES~~
6.	Toxicity Grade:	~~2~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~YES~~ ~~Is this serious event associated with congenital anomaly or birth defect?~~ ~~NO~~ ~~Did this serious event result in death?~~ ~~NO~~ ~~Did this serious event require or prolong hospitalization?~~ ~~NO~~ ~~Did this serious event result in persistent or significant disability/incapacity?~~ ~~NO~~ ~~Is this serious event life threatening?~~ ~~NO~~ ~~Other medically important serious event~~ ~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007425

***** THIS REPEATING FORM HAS BEEN DELETED *****

9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~fall~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~
12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~NOT RECOVERED/NOT RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[~~2020473499~~]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007426

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Neck Pain]
4.	Start Date Time:	Nov/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Fall]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007427

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right Shoulder Pain]
4.	Start Date Time:	Nov/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Fall]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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FDA-CBER-2021-5683-0007429

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007430

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007431

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007432

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	INFLUENZA VACCINE	Nov/30/2020	Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007433

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[INFLUENZA VACCINE]
5.	Date:	Nov/30/2020

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007434

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007435

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007436

Header Text: c4591001
Visit: Logs **Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007437

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007438

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007439

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007440

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007441

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007442

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007443

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007444

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007445

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007446

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007447

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007448

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007449

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007450

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007451

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Queries, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/16/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007452

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007453

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007454

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007455

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007456

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 12:38:34 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007457

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Aug-13-2020 19:37:20 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007458

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007459

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007460

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007461

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007462

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007463

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007464

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007465

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007466

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007467

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007468

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007469

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007470

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
7	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007471

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
8	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007472

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
9	Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007473

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007474

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007475

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007476

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007477

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007478

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007479

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007480

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007481

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007482

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007483

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007484

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007485

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007486

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007487

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007488

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007489

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007490

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007491

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007492

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007493

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.a	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007494

Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.b	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007495

Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.b	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007496

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007497

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.b	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007498

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007499

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.c	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007500

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.c	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007501

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.c	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007502

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.d	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007503

Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.d	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007504

Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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5.d	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007505

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.d	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007506

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.e	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007507

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.e	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007508

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.e	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007509

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007510

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Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007511

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5 f	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007512

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007513

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5 f	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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Confidential

FDA-CBER-2021-5683-0007514

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007515

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.g	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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Confidential

FDA-CBER-2021-5683-0007516

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.g	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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Confidential

FDA-CBER-2021-5683-0007517

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

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Generated By: pfe.levissc

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Item	Date	User	Comment
5.g	Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007518

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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Confidential

FDA-CBER-2021-5683-0007519

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007520

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
2	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007521

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
3	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007522

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007523

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007524

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007525

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007526

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007527

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007528

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Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007529

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007530

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Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007531

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.c	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007532

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.c	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007533

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.c	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007534

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007535

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007536

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Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007537

Header Text: c4591001

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Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007538

Header Text: c4591001

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Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007539

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007540

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Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007541

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007542

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Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007543

Header Text: c4591001

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007544

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Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007545

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007546

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Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007547

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007548

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007549

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Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007550

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007551

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 h	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007552

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Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 h	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007553

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Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 h	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

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FDA-CBER-2021-5683-0007554

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Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5 h	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007555

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007556

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007557

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007558

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007559

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007560

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007561

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007562

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007563

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007564

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007565

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007566

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007567

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007568

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007569

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007570

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007571

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007572

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007573

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007574

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007575

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007576

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007577

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007578

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007579

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007580

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007581

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007582

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
6	Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007583

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007584

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007585

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007586

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007587

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007588

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 12:38:34 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Gabriela Obeidat	N/A	Feb-23-2021 16:38:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Feb-22-2021 14:22:24 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Gabriela Obeidat	N/A	Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007589

Van Tran	Approved	Nov-04-2020 09:28:37 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Nov-03-2020 10:01:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Oct-13-2020 19:21:06 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Sep-29-2020 18:38:37 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Sep-16-2020 14:25:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007590

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961017	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007591

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-13-2020 19:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-13-2020 19:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007592

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-13-2020 19:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/13/2020	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007593

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Subject ID

Date	Location	User	Value	Reason
Aug-13-2020 19:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961017	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-13-2020 18:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1956	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-13-2020 19:35:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-13-2020 19:35:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-13-2020 19:35:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** WHITE	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007594

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-13-2020 19:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Aug/13/2020	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007595

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-13-2020 19:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Aug/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-13-2020 19:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-13-2020 19:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007596

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Aug-13-2020 19:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** sulfa allergy **Start Date:** UNK/UNK/1960 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** sulfa allergy	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/1960	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007597

1.b

Date	Location	User	Value	Reason
Aug-13-2020 19:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** hyperlipidemia **Start Date:** UNK/UNK/2008 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** hyperlipidemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

1.c

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FDA-CBER-2021-5683-0007598

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-13-2020 19:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** seasonal allergies **Start Date:** UNK/UNK/1975 **Ongoing:** YES	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007599

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 07:42:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-13-2020 20:59:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify SEASONAL ALLEGIES as follows...If reporting SEASONAL ALLERGIES edit as such, otherwise clarify the term further. Thank you.
Aug-13-2020 19:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** seasonal allegies	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/1975	Initial Entry

1.c Ongoing:

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007600

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-13-2020 19:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-13-2020 19:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** appendectomy **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007601

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** appendectomy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2003	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2003	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-13-2020 19:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** appendicitis **Start Date:** UNK/UNK/2003	Initial Entry

Confidential
FDA-CBER-2021-5683-0007602
090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Ongoing: NO End Date: UNK/UNK/2003	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** appendicitis	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2003	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2003	Initial Entry

1.f

Date	Location	User	Value	Reason
Aug-19-2020 08:48:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Line/MH N** 6	New Information

Confidential

FDA-CBER-2021-5683-0007603

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			umber: **Medical History Term:** Gastrointestinal perforation **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	
Aug-18-2020 09:32:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** blood vessel tear **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	Changed Information
Aug-13-2020 19:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** vessel torn in small intestine **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007604

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-24-2020 17:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Closed	Response satisfies query
Aug-19-2020 08:48:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-19-2020 08:48:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Gastrointestinal perforation	New Information
Aug-18-2020 11:24:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Reissued:Opened	GPD MM: The term was fine as torn vessel in the small intestine and should be returned as such in medical history. The query was what was the etiology? Was it secondary to the appendicitis? It's best to consolidate terms to one major event.
Aug-18-2020 09:32:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-18-2020 09:32:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** blood vessel tear	Changed Information

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007605

Aug-17-2020 16:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Opened	GPD MM: Please clarify the etiology of the torn vessel in the small intestine.
Aug-13-2020 19:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** vessel torn in small intestine	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2003	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2003	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-20-2020 14:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** SURGERY FOR SMALL VESSEL **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	Changed Information

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007606

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Aug-13-2020 19:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** surgery for small vessel tear **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007607

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-21-2020 19:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-20-2020 14:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-20-2020 14:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** SURGERY FOR SMALL VESSEL	Changed Information
Aug-20-2020 08:08:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Reissued: Opened	Thank you for confirming; however, this term SURGERY FOR SMALL VESSEL TEAR still needs to be updated to

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007608

				SURGERY FOR SMALL VESSEL. Please reference original query.
Aug-18-2020 09:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	this was previously completed-refer to med hx field 1 f
Aug-13-2020 23:37:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term SURGERY FOR SMALL VESSEL TEAR. Split the term into SURGERY FOR SMALL VESSEL and SMALL VESSEL TEAR and submit separately. Thank you.

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007609

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** surgery for small vessel tear	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2003	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2003	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-13-2020 19:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** hernia **Start Date:** UNK/UNK/2008 **Ongoing:** NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007610

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** hernia	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2009	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-13-2020 19:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** hernia repair surgery **Start Date:** UNK/UNK/2009	Initial Entry

Confidential

FDA-CBER-2021-5683-0007611

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Ongoing: NO End Date: UNK/UNK/2009	

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** hernia repair surgery	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2009	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2009	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-13-2020 19:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Numb** 10	Initial Entry

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FDA-CBER-2021-5683-0007612

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			er: **Medical History Term:** right foot morton's **Start Date:** UNK/UNK/2012 **Ongoing:** NO End Date: UNK/UNK/2012	

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** right foot morton's	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2012	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2012	Initial Entry

1.k

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FDA-CBER-2021-5683-0007613

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-13-2020 19:47:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** torn meniscus in right knee **Start Date:** UNK/UNK/2015 **Ongoing:** NO End Date: UNK/UNK/2015	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007614

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:47:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:47:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** torn meniscus in right knee	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:47:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2015	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:47:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2015	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-19-2020 08:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Line/MH Number:** 12 **Medical History Term:** Right Knee surgery **Start Date:** UNK/UNK/2015	New Information

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FDA-CBER-2021-5683-0007615

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Ongoing: NO End Date: UNK/UNK/2015	
Aug-18-2020 22:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Line/MH Number:** 12 **Medical History Term:** torn meniscus right knee **Start Date:** UNK/UNK/2015 **Ongoing:** NO End Date: UNK/UNK/2015	New Information
Aug-13-2020 19:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 12 **Medical History Term:** right knee surgery for torn meniscus **Start Date:** UNK/UNK/2015 **Ongoing:** NO End Date: UNK/UNK/2015	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007616

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.l Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 12	Initial Entry

1.l Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-20-2020 08:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1 : Closed	Response satisfies query
Aug-19-2020 13:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2 : Closed	Discrepancy has been closed.
Aug-19-2020 08:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	New Information
Aug-19-2020 08:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Right Knee surgery	New Information
Aug-19-2020 06:28:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2 : Opened	Spacing: Verbatim Term contains leading, trailing or more than

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007617

				one consecutive space.
Aug-18-2020 22:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	New Information
Aug-18-2020 22:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** torn meniscus right knee	New Information
Aug-13-2020 20:59:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1 : Opened	Multiple concepts. Split the term RIGHT KNEE SURGERY FOR TORN MENISCUS into RIGHT KNEE SURGERY and RIGHT KNEE TORN MENISCUS.
Aug-13-2020 19:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** right knee surgery for torn meniscus	Initial Entry

1.l Start Date:

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007618

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Aug-13-2020 19:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2015	Initial Entry

1.l Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2015	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-13-2020 19:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 13 **Medical History Term:** right tivia tear **Start Date:** UNK/UNK/2009 **Ongoing:** NO End Date: UNK/UNK/2009	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007619

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 13	Initial Entry

1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 19:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** right tivia tear	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2009	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 19:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2009	Initial Entry

1.n

Date	Location	User	Value	Reason
Aug-13-2020 20:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 14 **Medical History Term:** vasectomy **Start Date:** UNK/UNK/1990	Initial Entry

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FDA-CBER-2021-5683-0007620

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Ongoing: NO End Date: UNK/UNK/1990	

1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 20:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 14	Initial Entry

1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 20:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** vasectomy	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 20:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/1990	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 20:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007621

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Aug/13/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 233.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 76.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007622

Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 28.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.0 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 97.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-13-2020 19:49:34	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0007623

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	ORAL CAVITY	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007624

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-13-2020 19:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Aug/13/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-13-2020 19:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 228445	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007625

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 19:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 19:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 19:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 19:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 19:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 19:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DS6	Initial Entry

Confidential

FDA-CBER-2021-5683-0007626

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 19:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DS6	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-13-2020 19:51:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DS7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 19:51:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DS7	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 19:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DS8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 19:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DS8	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 19:51:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHW6	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007627

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 19:51:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHW6	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-13-2020 19:52:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHW7	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 19:52:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHW7	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007628

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 19:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 19:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 19:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 19:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 19:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 19:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DRJ	Initial Entry

Confidential

FDA-CBER-2021-5683-0007629

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 19:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DRJ	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007630

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Aug/13/2020 17:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007631

Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-13-2020 19:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007632

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-13-2020 19:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES - REACTOGENICITY E-DIARY COLLECTED FOR TH IS SUBJECT	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007633

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 18:42:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/1/2020	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007634

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Symptom::** FA	Initial Entry

Confidential

FDA-CBER-2021-5683-0007635

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)		(pfe.lmartinez1)	TIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** HEADACHE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007636

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** CHILLS **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007637

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.e

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** DIARRHEA **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007638

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007639

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** NEW OR WORSENED JOINT PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007640

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NEW OR WORSENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** REDNESS **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

Confidential

FDA-CBER-2021-5683-0007641

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction ::** SWELLING **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007642

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 18:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007643

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 18:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.5 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** F	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007644

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 18:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007645

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 19:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 19:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 19:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 19:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 19:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 19:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP96DD	Initial Entry

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FDA-CBER-2021-5683-0007646

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Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 19:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP96DD	Initial Entry

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FDA-CBER-2021-5683-0007647

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 03:58:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Closed	97.5 CORRECT DATA
Sep-09-2020 08:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	97.5 CORRECT DATA
Sep-08-2020 12:57:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sumit Jain (pfe.jains90)	Query 1: Opened	eDiary: Per eDiary records, e-Diary Temperature value(s) recorded is < 94 F (34.4 C). Please confirm if the thermometer recording from subject or the entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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				is appropriate. Thanks.
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/1/2020 10:28	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-01-2020 18:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

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Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961017 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 00:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Updated per query
Nov-05-2020 17:53:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	COVID ILLNESS visit dated 29Oct2020 is now entered
Nov-02-2020 03:24:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Opened	RQ1: Previous response states 'will update illness visit' however no Covid Illness visit reported that corresponds with Illness eDiary response on 20OCT2020. Please update or clarify.
Oct-30-2020 01:13:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Candidate	Query response indicate will update illness visit. Please query after 2 days to confirm whether Cov ill visit is updated or not.
Oct-29-2020 20:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	will update illness visit
Oct-29-2020 11:12:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe.nairs51)	Query 1: Opened	Illness ediary: As per Illness ediary records, subject reported "Yes" for the question "Have you experienced

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				any of the following?" for the COVID-19 symptoms or diagnosis on 20OCT2020. But corresponding COVID Illness visit not reported. Please clarify.
Sep-30-2020 13:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/29/2020	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** **Symptom::** FA	Initial Entry

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Time (US & Canada)		(pfe.gobeidat)	TIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	

2.b Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** HEADACHE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

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2.c Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** CHILLS **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

2.e

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** DIARRHEA **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007655

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.f Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007656

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.g Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Symptom::** NEW OR WORSENED JOINT PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007657

2.h Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NEW OR WORSENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Injection Site Reaction::** RE DN ESS **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Injection Site Reaction::** SWELLING **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007659

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 13:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007660

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 18:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 18:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 18:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 18:38:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/29/2020	Transcription Error
Sep-29-2020 18:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 18:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007661

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Sep-29-2020 18:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNH2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 18:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZNH2	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 18:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNVTLX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 18:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNVTLX	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 18:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNVTLY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 18:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNVTLY	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007662

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 18:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/23/2021	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007663

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 18:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 18:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 11:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-24-2021 05:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 18:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 18:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Feb/23/2021	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007664

5.a

Date	Location	User	Value	Reason
Feb-24-2021 11:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BNZNMH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 11:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BNZNMH	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-24-2021 11:33:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSH4KG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 11:33:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSH4KG	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 11:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSH4KH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 11:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSH4KH	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007665

Header Text: c4591001
Visit: V6_MONTH24_L
Form: DATE OF VISIT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 14:51:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Steven Finelli (pfe finels)	Query 3: Closed	data confirmed
Mar-02-2021 11:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 3: Answered	date is unable to be erased once entered this is why erroneous visit it ticked.
Mar-02-2021 03:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 3: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-02-2021 02:17:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	Erroneous Visit is marked,
Mar-01-2021 15:03:11 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Rivkah Rosen (pfe rosenr16)	Query 2: Closed	Response satisfies query

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007666

Canada)				
Mar-01-2021 11:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	this was entered in error
Mar-01-2021 11:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 2: Answered	corrected
Mar-01-2021 11:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-25-2021 22:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW7444554;The Date of Visit at Visit 'V6MTH24' is the same as the other Date of Visit at Visit 'V4MTH6'. Please review for duplication and update as appropriate.
Feb-25-2021 04:29:30 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Opened	PDQ: DOV at this visit is out of window (-539 day) from DOV (01/Sep /2020) at

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FDA-CBER-2021-5683-0007667

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Canada)				V1D1VX1L. Please reconcile and update accordingly, else confirm date is correct as is.
Feb-23-2021 17:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/23/2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-01-2021 11:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** ERRONEOUS VISIT	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007668

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Not Applicable	Initial Entry
Mar-01-2021 11:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Feb-23-2021 18:00:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Not Applicable	Initial Entry
Mar-01-2021 11:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Feb-23-2021 18:00:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry
Mar-01-2021 11:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:**	Transcription Error

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007669

Mar-01-2021 11:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-24-2021 05:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 18:00:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 18:00:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Feb/23/2021	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-01-2021 11:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 11:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:**	Transcription Error
Mar-01-2021 11:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNMH	Initial Entry

5.a Sample ID

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007670

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Mar-01-2021 11:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:**	Transcription Error
Mar-01-2021 11:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZNMH	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-01-2021 11:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:**	Transcription Error
Mar-01-2021 11:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH4KG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:**	Transcription Error
Mar-01-2021 11:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH4KG	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 11:19:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:**	Transcription Error
Mar-01-2021 11:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH4KH	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007671

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:19:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:**	Transcription Error
Mar-01-2021 11:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH4KH	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007672

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Nov-03-2020 10:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-03-2020 10:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-03-2020 10:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-03-2020 10:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/29/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-03-2020 10:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** COVID_A	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007673

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/29/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/20/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-07-2020 15:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO Date of Last Symptom Resolved: Oct/31/2020	Data updated
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007674

Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF	Initial Entry

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FDA-CBER-2021-5683-0007675

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			BREATH **Symptom Present:** NO	

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007676

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

4.e

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom Present:** NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW LOSS OF TASTE OR SMELL **Symptom Present:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007677

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW LOSS OF TASTE OR SM ELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.h

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007678

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007679

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 10:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 10:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms - Other:** nasal congestion	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** nasal congestion	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007680

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007681

Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-03-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007682

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Nov-03-2020 10:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 10:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-03-2020 10:04:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 10:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 10:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Oct/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 10:04:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** CV11242	Initial Entry

Confidential

FDA-CBER-2021-5683-0007683

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 10:04:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** CV11242	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007684

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Nov-03-2020 10:04:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 10:04:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 11:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 1: Closed	Response satisfies query
Nov-04-2020 09:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-03-2020 12:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe nedrickc)	Query 1: Reissued:Opened	DM: Please enter site comment in Field #4 'If no sample was collected or sample was not collected according to protocol, please provide reason.'
Nov-03-2020 10:07:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	home swab was done
Nov-03-2020 10:04:49 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007685

Time (US & Canada)				marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Nov-03-2020 10:04:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-04-2020 09:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** home swab was collected	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007686

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007687

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** YES *Number of Visits or Contacts:* 1	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007688

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES *Number of Visits or Contacts:* 1	Initial Entry

1.d

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:** NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.e

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007689

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:** NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007690

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-03-2020 10:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007691

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007692

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Nov-03-2020 10:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007693

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-03-2020 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-03-2020 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES *Respiratory Illness Diagnosis:* upper respiratory tract infection Date of Diagnosis: Oct/22/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007694

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007695

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0007696

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007697

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.b

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007698

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007699

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007700

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007701

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007702

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007703

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007704

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007705

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007706

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007707

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007708

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007709

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0007710

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007711

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.b

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007712

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007713

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007714

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007715

			tifier:	ne	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007716

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007717

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier:	ne
			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007718

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007719

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007720

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007721

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007722

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007723

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007724

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

Confidential

FDA-CBER-2021-5683-0007725

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

			tifier: ne **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007726

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007727

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007728

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007729

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** Not Done **Systolic::** Not Done **Diastolic::** Not Done **Respiratory Rate in respirations/minute:** Not Done **Heart Rate in beats/minute:** Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Diastolic:

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007730

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007731

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** Not Done **Oxygen Saturation:** Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-03-2020 10:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007732

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-03-2020 10:08:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007733

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007734

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

6. Ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 10:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007735

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/29/2020 **Form:** IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-03-2020 10:09:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007736

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/07/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Dec-07-2020 15:13:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Dec/7/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-07-2020 15:13:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** COVID_A1	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007737

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/07/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Dec-07-2020 15:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 15:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 15:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 15:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-07-2020 15:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 15:13:49 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0007738

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/07/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(pfe rgutierrez)	**Sample ID:** BSJ600	

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 15:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** BSJ600	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 15:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sample ID:** BSJ601	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 15:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** BSJ601	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 15:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sample ID:** BR856J	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 15:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** BR856J	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007739

Header Text: c4591001
Visit: End of Treatment - Unscheduled
Form: DISPOSITION - TREATMENT - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:55
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-08-2020 17:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-08-2020 17:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 08:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-08-2020 17:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-08-2020 17:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** COMPLETED	Initial Entry
Oct-01-2020 13:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please complete the End of Treatment CRF. Per Guidelines, If the Participant receives all vaccinations as per protocol and completes the follow-up visit procedures within the 1-month post

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007740

				vaccination period, report the status as COMPLETED.

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007741

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Dec-23-2020 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Undeleted	Transcription Error
Dec-01-2020 13:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	Transcription Error
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007742

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Dec-23-2020 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Undeleted	Transcription Error
Dec-01-2020 15:58:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	Transcription Error
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007743

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Jan-26-2021 14:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Form Undeleted	Changed Information
Jan-11-2021 14:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	Transcription Error
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007744

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Dec-01-2020 15:50:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	Transcription Error
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007745

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Dec-08-2020 16:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	New Information
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007746

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Dec-08-2020 16:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	New Information
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007747

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Dec-23-2020 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Undeleted	Transcription Error
Dec-08-2020 16:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	New Information
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007748

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Dec-23-2020 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Undeleted	Transcription Error
Dec-08-2020 16:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Deleted	New Information
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007749

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-04-2021 11:19:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	Query closed; will follow for requested clinical case information.
Feb-03-2021 12:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 6: Answered	medical records are still pending
Feb-03-2021 10:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Opened	Clinical Followup - please submit to SAE head injury description/symptoms, imaging (XRAY/CT/etc) and neurological evaluation.
Feb-01-2021 20:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Jan-26-2021 15:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 5: Answered	AE 3 updated to Fall and SAE criterion removed. Unable to

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007750

				remove the SAE number please unlock the line.
Jan-21-2021 00:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	Clinical - A traumatic accident of a fall needs to be reported recorded as an AE, even if an injury did not result. See CRF completion guidelines Sect. 8.17.4.2/falls.
Jan-15-2021 14:41:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Jan-12-2021 11:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 4: Answered	data updated
Jan-11-2021 19:13:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	SAE for broken sacrum has been re-entered
Jan-11-2021 17:32:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	CLINICAL Please submit a SAE safety update with further information on the event Head Injury, including location (superficial, cranial, brain), symptoms and results of the evaluation for this injury.
Jan-11-2021 17:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Event term is Head Injury; however, SAE report has term 'Head Injury and Broken Sacrum'. Please submit a SAE safety update FAX if event term is Head injury alone.

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007751

Dec-04-2020 01:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Closed	AE deleted
Dec-03-2020 13:03:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Candidate	AE deleted
Dec-03-2020 13:03:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	AE deleted
Dec-01-2020 13:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-01-2020 13:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-01-2020 10:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Please submit a SAE safety update with further information on the event Head Injury, including location (superficial, cranial, brain), symptoms and results of the evaluation for this injury.
Dec-01-2020 10:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE report states subject had a 'fall at home". Per CRF Completion guidelines Sect 8.50.2.2, a fall should be entered as an separate adverse event, with a description of the fall.
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Head Injury	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0007752

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-30-2020 15:56:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/29/2020 UNK:UNK	Transcription Error
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-23-2020 12:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO End Date Time: Dec/17/2020 UNK:UNK	New Information
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 10:59:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 3	Transcription Error
Jan-12-2021 11:33:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 4	New Information
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may

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require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-20-2021 23:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 7: Closed	Response satisfies query
Jan-20-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Deleted	Close Auto Query
Jan-20-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Answered	Transcription Error
Jan-20-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect ? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life	Transcription Error

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			threatening? NO Other medically import ant serious event NO	
Jan-20-2021 11:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 7: Reissued:Open ed	CLINICAL Head Injury event serious criteria are NOT SAE; however, most recent SAE report has Head Injury as YES SAE based on medically Imp criterion. Event Head injury needs to have the same serious level in both AE and SAE. Please update where needed
Jan-20-2021 10:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Candidate	For AE Head Injury: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Jan-20-2021 10:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Answered	Transcription Error
Jan-20-2021 10:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Transcription Error
Jan-13-2021 17:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 7: Reissued:Open ed	CLINICAL Thank you. Please submit a SAE safety followup to harmonize reporting of the serious criterion 'Life-threatening' for the event of Head Injury; SAE report has criterion of 'Medically Important' currently

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Jan-12-2021 11:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 7: Answered	data updated
Jan-11-2021 17:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 7: Opened	Clinical Event of Head Trauma serious criteria is Life Threatening; however, in SAE report serious criteria is Med Important. Also severity grade is 2, whereas Life Threatening would be 4. Please review serious criteria, harmonize reporting, and update
Jan-11-2021 17:24:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	event of Head Injury is returned to SAE
Jan-11-2021 17:23:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Jan-11-2021 13:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Jan-11-2021 13:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error
Jan-11-2021 13:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect ? NO Did this serious event result in death?	Transcription Error

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			NO Did this serious event r equire or prolong hospi talization? NO Did this serious event r esult in persistent or sig nificant disability/incap acity? NO Is this serious event life threatening? YES Other medically import ant serious event NO	
Jan-08-2021 05:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 6: Reissued:Open ed	SAE RECON 1: The event head Injury was reported as serious in Safety database. Please confirm seriousness.If needs to be downgraded to non serious, please submit a follow up form.
Jan-07-2021 19:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Reissued:Open ed	The Fall SAE is reported itself & a fall could occur with no fracture or other injury. Please assess the event for serious criteria and report as a SAE if the event meets one or more criteria (including disability)
Jan-07-2021	ACV0PFEINFP6000	Rocio	Query 6: Answered	AE is result of SAE of Fall

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18:11:58 (UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe rgutierrez)		and reported in SAE form as such. Please advise.
Jan-07-2021 18:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 5: Answered	AE is result of SAE of Fall and reported in SAE form as such. Please advise.
Dec-31-2020 01:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 6: Opened	SAE RECON:AER#2020473499 Head injury(onset date:29Nov2020)was reported as serious in Safety database but nonserious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-31-2020 01:44:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Closed	Response satisfies query

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-30-2020 03:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 4: Opened	For AE Head Injury: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Dec-23-2020 15:59:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	CLINICAL Serious criteria for event of Head Injury are NO; however, SAE report has Head Injury as a SAE based on the criterion of Medically Important/ Significant. Please review, harmonize reporting, and update in the appropriate location.
Dec-23-2020 12:54:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Head Injury: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Dec-23-2020 12:54:48 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

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Time (US & Canada)				
Dec-23-2020 12:54:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	New Information
Dec-23-2020 12:52:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Dec-23-2020 12:52:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life thre	New Information

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			atening? NO Other medically important s erious event NO	
Dec-04-2020 01:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 2: Closed	AE deleted
Dec-03-2020 13:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Candidate	AE deleted
Dec-01-2020 13:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-01-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - SAE criterion is 'Hospitalization'; however, SAE report criterion states only 'Medically Significant'. Please review, harmonize reporting, and update in the appropriate location. Note 2 criteria is an acceptable option.
Dec-01-2020 03:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Head Injury: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event

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				Number" is blank.
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-07-2021 19:02:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-07-2021 18:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-07-2021 18:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : OTHER *If Other, specify:* Fall	Transcription Error
Dec-27-2020 09:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Please update or clarify this OTHER Relationship for the event. The choice of Non-Drug Treatments means a Procedure/Surgery caused this HEAD INJURY. Is that correct? If Pt Fell, refer to CRF 8.50.2.2 Specific Guidance for Falls.
Dec-01-2020 14:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Dec-01-2020 13:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Dec-01-2020 08:10:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Please update or clarify this Relationship for Head Injury. The choice of Non-Drug Treatments means a Procedure/Surgery caused this HEAD INJURY. Is that correct? If Pt Fell, refer to CRF 8.50.2.2. Specific Guidance for Falls.
Nov-30-2020 15:56:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : CONCOMITANT NON-DRUG TREATMENT	Transcription Error
Nov-30-2020 15:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : OTHER	New Information
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Jan-20-2021 23:56:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-20-2021 11:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-20-2021 11:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Transcription Error
Jan-13-2021 17:22:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL SAE report states that a seizure prophylaxis medication was prescribed due to Head Injury event. Please review Con Medication given, and update if required
Jan-13-2021 17:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	will re-word
Jan-13-2021 17:21:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE report states that a seizure prophylaxis medication was prescribed due to Head Injury event. Please review Con Medication given, and update if required.
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-28-2021 08:33:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 2: Closed	Response satisfies query
Jan-26-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 2: Answered	follow up sent to Safety DB as resovled; please clarify
Jan-21-2021 01:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Reissued :Opened	SAE RECON 1:outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome.
Jan-20-2021 11:05:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Jan-20-2021 11:05:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RECOVERED/RESOLVED	Transcription Error
Jan-20-2021 11:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Head Injury: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

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Jan-20-2021 11:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-20-2021 11:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Transcription Error
Jan-13-2021 04:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020473499,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-23-2020 12:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-23-2020 12:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RECOVERED/RESOLVED	New Information
Dec-23-2020 12:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Head Injury: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-30-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-01-2020 03:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020473499	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-20-2021 11:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	event Broken Sacrum was made a SAE
Jan-13-2021 17:27:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL As event of Broken Sacrum is not a SAE, please submit a SAE safety update removing the 2nd half of the event term 'Head Injury and Broken Sacrum'
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BROKEN SACRUM	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

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Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-21-2021 06:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 11: Closed	no longer listed in SDB listing as of today
Jan-21-2021 01:16:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 11: Opened	SAE RECON: AER#202047349, broken sacrum was updated to non serious in AE CRF while recorded as serious in Safety database.Please confirm seriousness and update CRF. If safety update is required, submit a follow-up SAE

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				Form.
Jan-20-2021 23:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Jan-20-2021 16:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 10: Deleted	Close Auto Query
Jan-20-2021 16:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Closed	Close Auto Query
Jan-20-2021 16:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Transcription Error
Jan-20-2021 11:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 8: Closed	Broken sacrum is now a SAE
Jan-20-2021 11:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 10: Candidate	For AE BROKEN SACRUM: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-20-2021 11:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Jan-20-2021 11:07:38 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Answered	New Information

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Time (US & Canada)				
Jan-20-2021 11:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Jan-20-2021 11:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	New Information
Jan-13-2021 17:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical Yes it is possible - click the AE term line & at the bottom of the screen should be a

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				'Select Action' drop down menu; use Undelete.
Jan-13-2021 17:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	Response satisfies query
Jan-13-2021 04:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 8: Opened	SAE RECON: AER#202047349, broken sacrum was recorded as non serious in AE CRF while recorded as serious in Safety database.Please confirm seriousness and update CRF. If safety update is required, submit a follow-up SAE Form.
Jan-12-2021 13:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Closed	Close Auto Query
Jan-12-2021 13:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Jan-12-2021 13:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Transcription Error
Jan-12-2021 13:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as

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				appropriate.
Jan-12-2021 13:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Jan-12-2021 13:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Transcription Error
Jan-12-2021 11:38:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 4: Answered	unable to undelete and update "fall" ae
Jan-11-2021 20:47:56	ACV0PFEINFP6000	Kathryn	Query 6: Opened	CLINICAL Broken

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(UTC-06:00) Central Time (US & Canada)		Sewell (pfe.sewelk02)		sacrum Serious criterion is Life-Threatening; however severity grade is 2. As per protocol Sect 10.3.3 Life Threatening =Gr 4 severity. Also SAE report serious criterion for Broken Sacrum is Med Important. Please harmonize reporting/update
Jan-11-2021 20:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical - It appears that the event FALL has been removed; however, per CRF completion guidelines Sect 8.17.4.2, a traumatic fall must be recorded as an AE
Jan-11-2021 14:00:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	For AE BROKEN SACRUM: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-11-2021 14:00:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Jan-11-2021 14:00:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO	Transcription Error

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			Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	
Jan-07-2021 19:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	CLINICAL The Fall SAE is reported itself & a fall could occur with no fracture or other injury. Please assess the event for serious criteria and report as a SAE if the event meets one or more criteria (including disability)
Jan-07-2021 18:13:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 4: Answered	AE is result of SAE of Fall and reported in SAE form as such. Please advise.
Dec-23-2020 16:00:29	ACV0PFEINFP6000	Kathryn	Query 4: Opened	CLINICAL Serious

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(UTC-06:00) Central Time (US & Canada)		Sewell (pfe.sewelk02)		criteria for event of broken Sacrum are NO; however, SAE report has broken Sacrum as a SAE based on the criterion of Medically Important/ Significant. Please review, harmonize reporting, and update in the appropriate location.
Dec-23-2020 12:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-23-2020 12:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Transcription Error
Dec-23-2020 12:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE BROKEN SACRUM: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-01-2020 15:58:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-30-2020 15:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-30-2020 15:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO	Transcription Error

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			Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE BROKEN SACRUM: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for

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				serious events. Please review and update as appropriate.
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Nov-30-2020 15:57:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-04-2021 11:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Feb-03-2021 12:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information

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FDA-CBER-2021-5683-0007780

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-03-2021 12:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : OTHER *If Other, specify:* Fall	Changed Information
Feb-03-2021 10:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical Please update or clarify this OTHER Relationship for the event. The choice of Non-Drug Treatments means a Procedure/Surgery caused 'Broken Sacrum'. Is that correct; note AE of Fall on the same day.
Jan-20-2021 16:47:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : CONCOMITANT NON-DRUG TREATMENT	Transcription Error
Jan-07-2021 19:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-07-2021 18:13:24 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error

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Time (US & Canada)				
Jan-07-2021 18:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : OTHER *If Other, specify:* Fall	Transcription Error
Dec-27-2020 09:10:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical Please update or clarify this OTHER Relationship for the event. The choice of Non-Drug Treatments means a Procedure/Surgery caused this BROKEN SACRUM. Is that correct? If Pt Fell, refer to CRF 8.50.2.2 Specific Guidance for Falls.
Dec-02-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 2: Closed	Monitor will f/u to get data corrected.
Dec-01-2020 15:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 2: Answered	Original value is correct
Dec-01-2020 14:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 2: Opened	CLINQUERY: Per the SAE Report provided, the BROKEN SACRUM was Due to a Fall at Home. Therefore, please confirm the

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				Relationship (CAUSALITY) field should be updated to FALL AT HOME. Please update or provide clarification.
Dec-01-2020 14:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Need updated query
Dec-01-2020 08:10:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Please update or clarify this Relationship for Broken Sacrum. The choice of Non-Drug Treatments means a Procedure/Surgery caused this BROKEN SACRUM. Is that correct? If Pt Fell, refer to CRF 8.50.2.2. Specific Guidance for Falls.
Nov-30-2020 15:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : CONCOMITANT NON-DRUG TREATMENT	Transcription Error
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to : OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

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Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-20-2021 11:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RECOVERING/RESOLVING	Transcription Error
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-30-2020 15:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Jan-26-2021 14:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry
Jan-11-2021 14:02:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-26-2021 14:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry
Jan-11-2021 14:02:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-26-2021 14:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Fall	Initial Entry
Jan-13-2021	ACV0PFEINFP6000	Ricell Ann	Query 6:	event deleted in

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04:18:19 (UTC-06:00) Central Time (US & Canada)		Piojo (pfe.quitor)	Closed	CRF
Jan-11-2021 14:02:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Jan-11-2021 14:02:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:**	Transcription Error
Jan-08-2021 05:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 6: Reissued: Opened	SAE RECON 2: Event was reported as serious in Safety database. Please confirm seriousness for broken sacrum,
Jan-07-2021 18:14:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 6: Answered	Broken sacrum is in AE forms, please clarify.
Dec-31-2020 01:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 6: Reissued: Opened	SAE RECON 1: Head injury was added however, BROKEN SACRUM is still missing in AE CRF. Please confirm event seriousness. If serious, please add in AE CRF.

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				Otherwise,submit a follow up AEM form to downgrade event in Safety DB.
Dec-23-2020 15:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Dec-23-2020 13:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 6: Answered	Changed data per query
Dec-23-2020 13:00:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 5: Answered	Changed data per query
Dec-17-2020 06:56:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 6: Opened	SAE RECON: AER#202047349, head injury and broken sacrum inactivated in Inform while still recorded as SAEs in Safety database.Per CRF CG 8.50.2.2 When a fall results in an injury, both the injury and the fall should be recorded as AEs. Please confirm.
Dec-09-2020 12:12:20	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	CLINICAL SAE report reports

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(UTC-06:00) Central Time (US & Canada)				SAE of FALL, and the individual events of Head Injury and Broken Sacrum. Have these SAEs been deleted because they are not SAEs, or inadvertently? SAEs on AE CRF and SAE report must match; please update as appropriate.
Dec-03-2020 12:58:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow up on correct event
Dec-03-2020 12:05:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Closed	Discrepancy has been closed.
Dec-03-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Dec-03-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Fall	Transcription Error
Dec-02-2020 12:52:35 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 3: Answered	safety report was updated and faxed

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(US & Canada)				
Dec-02-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Monitor will f/u to get data corrected.
Dec-02-2020 05:16:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Opened	Multiple concepts in the term FALL RELATED INJURIES (HEAD INJURY & BROKEN SACRUM). Split the term into FALL and HEAD INJURY and BROKEN SACRUM and submit as 3 separate entries. Thank you.
Dec-01-2020 19:58:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Dec-01-2020 16:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Please submit a SAE safety update with further information on the event Head Injury, including location (superficial, cranial, brain), symptoms and results of the evaluation for this injury.

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Dec-01-2020 15:59:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-01-2020 15:59:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-01-2020 15:59:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Fall Related Injuries (head injury & broken sacrum)	New Information
Dec-01-2020 15:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Multiple concepts in the term FALL RELATED INJURIES. Split the term into FALL and INJURIES and report as separate entries. Thank you.
Dec-01-2020 14:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Per the SAE Report, please re-enter the Adverse Event of HEAD INJURY with a Relationship (CAUSALITY) of FALL AT HOME. Please update this AE Record with the AE of Head Injury.

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961017
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Fall Related Injuries	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-09-2020 12:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-07-2020 15:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per query
Dec-07-2020 15:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO End Date Time: Nov/29/2020 UNK:UNK	Per query
Dec-07-2020 07:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - please enter stop date for event of Fall, which was completed at the end of the fall.
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-01-2021 09:02:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Jan-26-2021 14:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Fall: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Jan-26-2021 14:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Changed Information
Dec-09-2020 12:06:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Dec-07-2020 15:34:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 3: Answered	confirmed.
Dec-04-2020 04:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 13:06:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - severity criteria for each AE should be determined alone; so please confirm

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				that the fall all by itself would be considered serious on the basis of requiring hospitalization? Injuries from fall are determined separately.
Dec-03-2020 13:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Deleted	move from candidate to open
Dec-03-2020 13:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Candidate	CLINICAL - severity criteria for each AE should be determined alone; so please confirm that the fall all by itself would be considered serious on the basis of requiring hospitalization? Fall injuries are determined separately.
Dec-03-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fall : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-01-2020 15:59:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fall Related Injuries (head injury & broken sacrum): Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fall Related Injuries: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

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			YES Did this serious event result i n persistent or significant disa bility/incapacity? NO Is this serious event life threat ening? NO Other medically important ser ious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-21-2020 10:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-18-2020 17:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated
Dec-18-2020 17:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treat ment(s), this event is due to: OTHER	updated

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			If Other, specify: Fall at home	
Dec-09-2020 12:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - Followup on relationship to 'concomitant non-drug treatment'; however, previous query stated this would be updated to 'fall at home'. Please clarify 'Other' causality for this SAE.
Dec-02-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Monitor will f/u to get data corrected.
Dec-01-2020 16:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	Original value is correct
Dec-01-2020 14:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Per the SAE Report provided, the HEAD INJURY was Due to a Fall at Home. Therefore, please confirm the Relationship (CAUSALITY) field should be updated to FALL AT HOME. Please update or provide clarification.
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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			CONCOMITANT NON-DRUG TREATMENT	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-07-2020 15:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-07-2020 15:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** RECOVERED/RESOLVED	Fall resolved on the same day subject fell. Updated per DM query.
Dec-07-2020 15:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Fall : Response to "What was the outcome of this adverse event?" is 'Not

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				Recovered/Not Resolved' but AE End Date/Time is present.
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-01-2020 13:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-01-2021 09:02:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	**Data Entry:**	not in SDB
Dec-04-2020 04:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020473499	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1 : Closed	Monitor will f/u to get data corrected.
Dec-02-2020 06:45:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 2 : Closed	Response satisfies query
Dec-01-2020 15:50:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Transcription Error
Dec-01-2020	ACV0PFEINFP6000	auto query (autoquery)	Query 1	Transcription

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***** THIS REPEATING FORM HAS BEEN DELETED *****

15:50:33 (UTC-06:00) Central Time (US & Canada)			: Answered	Error
Dec-01-2020 15:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2 : Opened	Multiple concepts in the term FALL RELATED INJURIES. Split the term into FALL and INJURIES and report as separate entries. Thank you.
Dec-01-2020 14:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1 : Opened	Per the SAE Report, the Patient had a FALL at Home. Therefore, per CRF Guidelines, this AE Term should just be FALL. The injuries of Head Injury and Broken Sacrum need be captured as separate AE Events. Please update the data accordingly.
Dec-01-2020 13:13:24	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:**	Initial Entry

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(UTC-06:00) Central Time (US & Canada)			Fall Related Injuries	

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-01-2020 15:50:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 13:13:24 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fall Related Injuries:

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***** THIS REPEATING FORM HAS BEEN DELETED *****

Time (US & Canada)				Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-02-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Monitor will f/u to get data corrected.
Dec-01-2020 15:50:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-01-2020 14:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: For the AE of FALL, the Relationship (CAUSALITY) field should reflect the SAE report which is FALL AT HOME. Please update the data accordingly.
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT NON-DRUG TREATMENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-01-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-09-2020 12:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	query on deleted AE
Dec-08-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 2: Answered	Original value is correct
Dec-03-2020 13:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Please submit a SAE safety update with further information on the event Head Injury, including location (superficial, cranial, brain), symptoms and results of the evaluation for this injury. Not included in 01Dec

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				update.
Dec-03-2020 12:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	will re-word
Dec-03-2020 12:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Please submit a SAE safety update with further information on the event Head Injury, including location (superficial, cranial, brain), symptoms and results of the evaluation for this injury.
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Head Injury	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Nov/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** 2	Initial Entry

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Time (US & Canada)		(pfe.lmartinez1)		

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-09-2020 12:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	query on deleted AE
Dec-08-2020 22:56:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 3: Closed	data deleted
Dec-08-2020 16:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 3: Answered	Original value is correct
Dec-08-2020 16:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Dec-08-2020 16:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-08-2020 16:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associa	New Information

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***** THIS REPEATING FORM HAS BEEN DELETED *****

			ted with congenital anomal y or birth defect? NO Did this serious event result in death? NO Did this serious event requi re or prolong hospitalizatio n? NO Did this serious event result in persistent or significant d isability/incapacity? NO Is this serious event life thre atening? NO Other medically important s erious event NO	
Dec-04-2020 04:04:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 12:56:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - SAE criterion is 'Hospitalization'; however, SAE report criterion for Head Injury states only 'Medically Significant'. Please

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				review, harmonize reporting, and update in the appropriate location. Note 2 criteria is an acceptable option.
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Head Injury : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO	Initial Entry

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***** THIS REPEATING FORM HAS BEEN DELETED *****

			Other medically important s erious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatm ent(s), this event is due to: OTHER *If Other, specify:* Fall	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

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FDA-CBER-2021-5683-0007810

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-03-2020 10:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-04-2020 04:04:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020473499	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Broken Sacrum	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Nov/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-09-2020 12:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	query on deleted AE
Dec-09-2020 00:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 3: Closed	Closed as logline is deleted
Dec-08-2020 16:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 3: Answered	Original value is correct
Dec-08-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Dec-08-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information

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***** THIS REPEATING FORM HAS BEEN DELETED *****

Dec-08-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	New Information
Dec-04-2020 04:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 12:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - SAE criterion is 'Hospitalization'; however, SAE report criterion for

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				Broken Sacrum states only 'Medically Significant'. Please review, harmonize reporting, and update in the appropriate location. Note 2 criteria is an acceptable option.
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Broken Sacrum: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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***** THIS REPEATING FORM HAS BEEN DELETED *****

			Is this serious event life threatening? NO Other medically important serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* fall	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason

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090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-03-2020 10:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-04-2020 04:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020473499	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Neck Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Nov/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Feb-03-2021 12:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	next scheduled visit is approaching and will follow up

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Feb-02-2021 16:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please determine if this AE is still Ongoing as it has been 64 Days since Onset Date.
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason

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Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Fall	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007820

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Dec-07-2020 15:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007821

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Right Shoulder Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Nov/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Feb-03-2021 12:47:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	next scheduled visit is approaching and will follow up

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007822

Feb-02-2021 16:34:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please determine if this AE is still Ongoing as it has been 64 Days since Onset Date.
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007823

Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Fall	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007824

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Dec-07-2020 15:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007825

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Feb-23-2021 18:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007826

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961017

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-23-2021 18:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-23-2021 18:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-23-2021 18:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-23-2021 18:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** INFLUENZA VACCINE	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-23-2021 18:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/30/2020	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007827

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Queries, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-23-2021 16:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/16/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-10-2021 19:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Opened	Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but Further Vaccination Confirmation CRF is not completed. Please review and update as appropriate.
Feb-23-2021 16:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0007828

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-08-2020 17:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-13-2020 19:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 19:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-08-2020 17:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/29/2020	Initial Entry
Aug-13-2020 19:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/13/2020	Initial Entry
Aug-13-2020 19:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/13/2020	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007829

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961017 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Sep-16-2020 14:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae30a0\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0007830

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007831

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/14/2020

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007832

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961031]
2.	Birth Date:	(b) (6)/1998
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007833

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/14/2020
2.	Erroneous Visit	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007834

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007835

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DISPOSITION - SCREENING
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/14/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007836

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INTERMITTENT HEADACHES]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CESAREAN SECTION]
	Start Date:	Jun/8/2016
	Ongoing:	NO End Date: Jun/8/2016
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MASTITIS]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MASTITIS REMOVAL SURGERY]
	Start Date:	Oct/UNK/2016
	Ongoing:	NO End Date: Oct/UNK/2016

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007837

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CAT ALLERGY]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

1 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ATHLETIC ASTHMA]
	Start Date:	UNK/UNK/2004
	Ongoing:	NO End Date: UNK/UNK/2008

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007838

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/14/2020
2.	Weight:	[192.8]
3.	Unit:	LB
4.	Height:	[60.5]
5.	Unit:	in
6.	Body Mass Index:	[37.0]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007839

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Lab Urinalysis		
1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/14/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007840

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/14/2020
2.	Randomization Number:	[51006]
3.	Randomization Group:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007841

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DTD]
5.b	Sample ID	[BP5DTR]
5.c	Sample ID	[BP5DTS]
5.d	Sample ID	[BPRHX0]
5.e	Sample ID	[BPRHX1]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007842

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DT8]

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FDA-CBER-2021-5683-0007843

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/14/2020 18:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007844

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT

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FDA-CBER-2021-5683-0007845

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/4/2020
2.	Erroneous Visit	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007846

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO

2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/21/2020

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2 f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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FDA-CBER-2021-5683-0007848

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/4/2020

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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Confidential

FDA-CBER-2021-5683-0007849

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Lab Urinalysis		
1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/4/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	POSITIVE
	Not Done:	

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FDA-CBER-2021-5683-0007850

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/4/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP9689]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007851

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	Not Done	Comments
2.	Treatment Name	Not Done [ ]	Comments
3.	Formulation:	Not Done	Comments
4.	Dose Date Time:	Not Done //	Comments
5.	Anatomical Location:	Not Done	Comments
6.	Body Side:	Not Done	Comments
7.	Route:	Not Done	Comments
8.	Actual Dose:	Not Done [ ]	Comments
9.	Unit:	Not Done	Comments
10.	Timeframe Subject Was Observed	Not Done	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done	Comments

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FDA-CBER-2021-5683-0007852

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007853

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	Not Applicable	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2 f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments

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2.h	Symptom:	NEW OR WORSENED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
3.	Injection Site Location:	Not Applicable	Comments
4.	Injection Site Body Side:	Not Applicable	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	Comments

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR851V]
5.b	Sample ID	[BSH40R]
5.c	Sample ID	[BSH40S]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007856

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

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FDA-CBER-2021-5683-0007857

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Oct/8/2020
2.	Date of First Symptom Started:	Oct/5/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/7/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4 f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[Nasal congestion]

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FDA-CBER-2021-5683-0007858

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 10-Oct-2020 16:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

5.b	Symptoms - Other Text:	[Intermittent headaches]

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FDA-CBER-2021-5683-0007859

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007860

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Microbiology Specimen

1.	Actual Date of Collection:	Not Done //	Comments
2.	Specimen Type:	Not Done	Comments
3.	Specimen Collection Location:	Not Done	Comments
4.	Assay Code and Description:	Not Done	Comments
5.	Device Type:	Not Done	Comments
6.	Trade Name:	Not Done	Comments
7.	Test Result:	Not Done	Comments
8.	Comments/Findings/Details:	Not Done [ ]	Comments
9.	Trade Name Other, Specify:	Not Done [ ]	Comments

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007861

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	Not Done	Comments
2.	Sample Type	Not Done	Comments
3.	Sample Collected?	Not Done	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Done [ ]	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done [ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007862

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR851R]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007863

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1 f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007864

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** RESPIRATORY TREATMENT
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007865

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable [ ]	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable	Comments
3.	Treatment:	Not Applicable	Comments
4.	Treatment:	Not Applicable [ ]	Comments
5.	Start Date:	Not Applicable //	Comments
6.	Ongoing?	Not Applicable	Comments

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007866

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Illness Details			
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO	Comments
3.	Toxicity Grade:	1	Comments

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007867

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007868

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Illness Details			
1.	Category of Clinical Event:	Not Applicable	Comments
2.	Subcategory of Clinical Event:	Not Applicable	Comments
3.	Was a diagnosis obtained?	Not Applicable	Comments
4.	Toxicity Grade:	Not Applicable	Comments

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Form Version: 30-Jul-2020 21:27
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable		Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable

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Lab Chemistry Details

1.	Lab Panel:	Not Applicable	Comments
2.	Laboratory Name and Address	Not Applicable [ ]	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Specimen Type:	Not Applicable	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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5.b	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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5.d	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.e	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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FDA-CBER-2021-5683-0007873

5 f	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 30-Jul-2020 21:28
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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FDA-CBER-2021-5683-0007875

Laboratory Data Hematology

1.	Lab Panel:	Not Applicable	Comments
2.	Laboratory Name and Address	Not Applicable [ ]	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Specimen Type:	Not Applicable	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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5.b	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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FDA-CBER-2021-5683-0007877

5.d	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.e	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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5 f	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

5.g	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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FDA-CBER-2021-5683-0007879

5.h	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.i	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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FDA-CBER-2021-5683-0007880

5.j	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

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FDA-CBER-2021-5683-0007881

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - COVID
Form Version: 30-Jul-2020 21:27
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	**Record Identifier:**	**Systolic:**	**Diastolic:**	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007882

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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eCRF Audit Trail History

Vital Signs

1.	Date:	Not Applicable //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Applicable 1	
	Systolic:	Not Applicable [ ]	Comments
	Diastolic:	Not Applicable [ ]	Comments
	Respiratory Rate in respirations/minute:	Not Applicable [ ]	Comments
	Heart Rate in beats/minute:	Not Applicable [ ]	Comments

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FDA-CBER-2021-5683-0007883

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Form Version: 30-Jul-2020 21:28
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details	Form Instance
1.	Not Applicable	Record Identifier: / Oxygen Saturation Not Applicable / Not Applicable	Repeating Pages

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FDA-CBER-2021-5683-0007884

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Form Comments
eCRF Audit Trail History

Vital Signs

1.	Date:	Not Applicable //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Applicable 1	
	SPO2 Pulse Oximetry %	Not Applicable [ ]	Comments

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FDA-CBER-2021-5683-0007885

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Oxygenation Parameters			
1.	Date Time of Assessment:	Not Applicable //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable [ ]	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable [ ]	Comments

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FDA-CBER-2021-5683-0007887

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007888

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable [ ]	Comments
2.	Category:	Not Applicable	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable [ ]	Comments
5.	Start Date:	Not Applicable //	Comments
6.	Ongoing?	Not Applicable	Comments

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007889

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007890

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** IMAGING
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Form Comments
eCRF Audit Trail History

Imaging			
1.	Date of Assessment:	Not Applicable //	Comments
2.	Location of Assessment:	Not Applicable	Comments
3.	Type of Imaging Exam:	Not Applicable	Comments
4.	Assessment:	Not Applicable	Comments

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FDA-CBER-2021-5683-0007891

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/05/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A1

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007892

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/05/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR98YD]
5.b	Sample ID	[BSH43T]
5.c	Sample ID	[BSH43V]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007893

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007894

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

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FDA-CBER-2021-5683-0007895

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 22-Apr-2020 21:05 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Sep/4/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PREGNANCY
4.	Specify Status:	[ ]

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FDA-CBER-2021-5683-0007896

Header Text: c4591001	
Visit: Follow-Up - Unscheduled	**Form:** DISPOSITION - FOLLOW-UP
Form Version: 15-Sep-2020 21:53	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007897

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit | **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

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FDA-CBER-2021-5683-0007898

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007899

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	CHILLS	Aug/20/2020 UNK:UNK	NO End Date Time: Aug/21/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	EXPOSURE DURING PREGNANCY	Aug/14/2020 UNK:UNK	NO End Date Time: Sep/22/2020 UNK:UNK	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Nasal congestion	Oct/5/2020 UNK:UNK	NO End Date Time: Oct/10/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Sore throat	Oct/5/2020 UNK:UNK	NO End Date Time: Oct/7/2020 UNK:UNK	Repeating Pages
5. DELETED	ADVERSE EVENT	5	Intermittent headaches	Oct/5/2020 UNK:UNK	NO End Date Time: Oct/6/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	urinary tract infection	Jan/22/2021 UNK:UNK	YES	Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007900

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~1~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~CHILLS~~]
4.	Start Date Time:	~~Aug/20/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~NO~~ ~~End Date Time:~~ ~~Aug/21/2020 UNK:UNK~~
6.	Toxicity Grade:	~~2~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~
9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~PREGNANCY~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~
12.	Was a Non-Drug Treatment given?	~~NO~~

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FDA-CBER-2021-5683-0007901

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

13.	What was the outcome of this adverse event?:	~~RECOVERED/RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007902

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[2]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[EXPOSURE DURING PREGNANCY]	
4.	Start Date Time:	Aug/14/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 UNK:UNK	
6.	Toxicity Grade:	Not Applicable	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	Comments
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [PREGNANCY]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007903

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

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eCRF Audit Trail History
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Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~3~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~Nasal congestion~~]
4.	Start Date Time:	~~Oct/5/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~NO~~ ~~End Date Time:~~ ~~Oct/10/2020 UNK:UNK~~
6.	Toxicity Grade:	~~1~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~
9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~Personal illness~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~

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Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~RECOVERED/RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007906

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sore throat]
4.	Start Date Time:	Oct/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Personal illness]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007907

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0007908

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

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eCRF Audit Trail History
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Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~5~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~Intermittent headaches~~]
4.	Start Date Time:	~~Oct/5/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~NO~~ ~~End Date Time:~~ ~~Oct/6/2020 UNK:UNK~~
6.	Toxicity Grade:	~~1~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~
9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~Personal illness~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~

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Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~RECOVERED/RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0007910

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[urinary tract infection]
4.	Start Date Time:	Jan/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0007912

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007913

Header Text: c4591001
Visit: Logs - Unscheduled
Form: MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Form Status: Not Started
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007914

Header Text: c4591001
Visit: Logs
Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007915

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007916

Header Text: c4591001

Visit: Logs | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007917

Header Text: c4591001
Visit: Logs - Unscheduled
Form: CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Form Status: Not Started
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007918

Header Text: c4591001

Visit: Logs | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007919

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007920

Header Text: c4591001

Visit: Logs | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007921

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

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FDA-CBER-2021-5683-0007922

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007923

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007924

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007925

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007926

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007927

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007928

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/27/2021
2.	Erroneous Visit	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007929

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/27/2021

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007930

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BSH4FC]
5.b	Sample ID	[BSH4FB]
5.c	Sample ID	[BR85K4]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007931

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85K9]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007932

Header Text: c4591001	
Visit: V202_SURVEIL_SWAB 1 - Unscheduled Visit on Feb/10/2021	**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:22	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2

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Confidential

FDA-CBER-2021-5683-0007933

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled Visit on Feb/10/2021 | **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[AA10766]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007934

Header Text: c4591001	
Visit: V202_SURVEIL_SWAB 2 - Unscheduled Visit on Feb/24/2021	**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:22	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007935

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 - Unscheduled Visit on Feb/24/2021 | **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[AA10753]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007936

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007937

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007938

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Mar/1/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

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FDA-CBER-2021-5683-0007939

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007940

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Death Details		
1.	Date of Collection / Notification of Death:	//

Cause of Death		
2.	Cause of Death Status:	
	Cause of Death:	[ ]

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FDA-CBER-2021-5683-0007941

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007942

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/3/2021

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FDA-CBER-2021-5683-0007943

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

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FDA-CBER-2021-5683-0007944

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Mar/3/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

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FDA-CBER-2021-5683-0007945

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Lab Urinalysis		
1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/3/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007946

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNPY]
5.b	Sample ID	[BNVTNF]
5.c	Sample ID	[BNVTNG]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007947

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNR0]

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FDA-CBER-2021-5683-0007948

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/3/2021 11:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0007949

Header Text: c4591001

Visit: V102_VAX4	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007950

Header Text: c4591001

Visit: V102_VAX4	**Form:** LAB URINALYSIS - PREGNANCY TEST
Form Version: 20-Feb-2021 02:14	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.a	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

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FDA-CBER-2021-5683-0007951

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007952

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

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FDA-CBER-2021-5683-0007953

Header Text: c4591001

Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007954

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

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FDA-CBER-2021-5683-0007955

Header Text: c4591001

Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0007956

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

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Confidential

FDA-CBER-2021-5683-0007957

Header Text: c4591001

Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007958

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007959

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007960

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/4/2020

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007961

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007962

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 13:03:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007963

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Aug-14-2020 21:27:45 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007964

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Sep-09-2020 09:12:17 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	NOT VACCINATED DUE TO POSITIVE PREGNANCY TEST

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007965

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
Form	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007966

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
1	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007967

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
2	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007968

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
3	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007969

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
4	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007970

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
5	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007971

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
6	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007972

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
7	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
7	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007973

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
8	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
8	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007974

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
9	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
9	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007975

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
10	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
10	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007976

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
11	Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Done
11	Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007977

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 09:19:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Visit 3 delayed, Unplanned visit was completed

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007978

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007979

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007980

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007981

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.b	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007982

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.c	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007983

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.d	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007984

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.e	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007985

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.f	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007986

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.g	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007987

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.h	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007988

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007989

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007990

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007991

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0007992

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	subject did not receive 2nd vaccination Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007993

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
Form	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007994

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
1	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007995

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
2	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007996

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
3	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007997

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
4	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
4	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007998

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
5	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
5	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0007999

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
6	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
6	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008000

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
7	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
7	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008001

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
8	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
8	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008002

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
9	Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Done
9	Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	sample collected by site only Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008003

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	not done due to site collecting swab in office Not Done
Form	Oct-13-2020 14:44:38 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	NA due to site collecting swab
Form	Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008004

Header Text: c4591001

Visit: POT_COVID_ILL 1 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	not done due to site collecting swab in office Not Done
1	Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008005

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	not done due to site collecting swab in office Not Done
2	Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008006

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	not done due to site collecting swab in office Not Done
3	Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008007

Header Text: c4591001

Visit: POT_COVID_ILL 1 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	not done due to site collecting swab in office Not Done
4	Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008008

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:10:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	N/A

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008009

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008010

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008011

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008012

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008013

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008014

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008015

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008016

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
Form	Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008017

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
1	Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008018

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
2	Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008019

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-15-2020 09:21:17 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
3	Oct-13-2020 14:46:26 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable
3	Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
3	Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008020

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008021

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** ILLNESS DETAILS - SEVERE - Comments
Form Version: 17-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008022

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008023

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008024

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008025

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008026

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008027

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008028

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008029

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008030

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008031

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008032

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008033

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

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FDA-CBER-2021-5683-0008034

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008035

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008036

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008037

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008038

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008039

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008040

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008041

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008042

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008043

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008044

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008045

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008046

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008047

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008048

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008049

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008050

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008051

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008052

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008053

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008054

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008055

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008056

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008057

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008058

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008059

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008060

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008061

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008062

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008063

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008064

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008065

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008066

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008067

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008068

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008069

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008070

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008071

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008072

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008073

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008074

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008075

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008076

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008077

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008078

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008079

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008080

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008081

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008082

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008083

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008084

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008085

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008086

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008087

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008088

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008089

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008090

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008091

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008092

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008093

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008094

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008095

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

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FDA-CBER-2021-5683-0008096

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008097

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008098

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008099

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008100

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008101

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008102

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008103

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008104

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008105

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008106

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008107

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008108

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008109

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008110

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008111

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008112

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008113

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008114

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008115

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

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Confidential

FDA-CBER-2021-5683-0008116

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008117

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008118

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008119

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008120

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008121

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008122

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008123

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008124

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008125

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008126

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008127

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008128

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Nov-12-2020 16:07:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	not applicable per DM Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008129

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - Comments
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961031	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
7	Oct-09-2020 12:02:23 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	site determined this is not considered an SAE so status has been changed

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008130

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Mar-04-2021 13:50:20 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Applicable

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008131

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 13:03:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rocio Gutierrez	N/A	Feb-24-2021 15:46:00 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Feb-22-2021 14:29:41 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rocio Gutierrez	N/A	Dec-28-2020 16:32:51 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-13-2020 13:49:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008132

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rocio Gutierrez	N/A	Nov-13-2020 12:06:20 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-12-2020 16:07:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Nov-12-2020 16:07:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-06-2020 17:21:00 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Nov-05-2020 18:08:57 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008133

Affidavit:
N/A

Van Tran	Approved	Oct-30-2020 14:50:16 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Oct-29-2020 18:07:53 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Oct-23-2020 18:41:29 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008134

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-14-2020 21:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-14-2020 21:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008135

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-14-2020 21:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/14/2020	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008136

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-14-2020 21:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961031	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6) /1998	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-14-2020 21:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-14-2020 21:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-14-2020 21:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** WHITE	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008137

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-14-2020 21:27:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/14/2020	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008138

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-14-2020 21:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-14-2020 21:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-14-2020 21:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008139

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Aug-14-2020 21:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** INTERMITTENT HEADACHES **Start Date:** UNK/UNK/2005 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 21:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 21:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** INTERMITTENT HEADACHES	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 21:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-14-2020 21:30:02	ACV0PFEINFP6000	auto calc	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0008140

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)		(autocalc)	**Line/MH Number:** 2 **Medical History Term:** CESAREAN SECTION **Start Date:** Jun/8/2016 **Ongoing:** NO End Date: Jun/8/2016	

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** CESAREAN SECTION	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Jun/8/2016	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: Jun/8/2016	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-14-2020 21:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3	Initial Entry

Confidential

FDA-CBER-2021-5683-0008141

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Medical History Term: MASTITIS **Start Date:** UNK/UNK/2016 **Ongoing:** NO End Date: UNK/UNK/2016	

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** MASTITIS	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2016	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 21:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2016	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-14-2020 21:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4	Initial Entry

Confidential
FDA-CBER-2021-5683-0008142
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Medical History Term: MASTITIS REMOVAL SURGERY **Start Date:** Oct/UNK/2016 **Ongoing:** NO End Date: Oct/UNK/2016	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** MASTITIS REMOVAL SURGERY	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/UNK/2016	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: Oct/UNK/2016	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-14-2020 21:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** CAT ALLERGY	Initial Entry

Confidential

FDA-CBER-2021-5683-0008143

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Start Date: UNK/UNK/2000 **Ongoing:** YES	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** CAT ALLERGY	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2000	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 21:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Aug-14-2020 21:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** ATHLETIC ASTHMA **Start Date:** UNK/UNK/2004 **Ongoing:** NO **End Date:** UNK/UNK/2008	Initial Entry

Confidential
FDA-CBER-2021-5683-0008144
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 21:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 21:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ATHLETIC ASTHMA	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2004	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 21:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2008	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008145

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Date:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 192.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 60.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 37.0	Initial Entry

7.a

Confidential
FDA-CBER-2021-5683-0008146

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 98.4 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008147

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113	Initial Entry

Confidential

FDA-CBER-2021-5683-0008148

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:27
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

			Result:: NEGATIVE **Not Done::**	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NEGATIVE	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008149

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-18-2020 09:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-18-2020 09:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 51006	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008150

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-14-2020 21:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-14-2020 21:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-14-2020 21:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 21:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 21:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 21:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DTD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 21:31:30	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0008151

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BP5DTD	

5.b

Date	Location	User	Value	Reason
Aug-14-2020 21:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DTR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 21:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DTR	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-14-2020 21:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DTS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 21:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DTS	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-14-2020 21:31:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHX0	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 21:31:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHX0	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008152

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.e

Date	Location	User	Value	Reason
Aug-14-2020 21:32:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHX1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 21:32:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHX1	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008153

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-14-2020 21:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-14-2020 21:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-14-2020 21:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 21:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 21:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 21:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DT8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 21:30:54	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0008154

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BP5DT8	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008155

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/14/2020 18:11	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LEFT	Initial Entry

7. Route:

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008156

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-14-2020 21:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008157

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-14-2020 21:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008158

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-04-2020 23:11:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/4/2020	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008159

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-10-2020 04:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Closed	Site: NOT VACCINATED DUE TO POSITIVE PREGNANCY TEST
Sep-09-2020 09:12:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	NOT VACCINATED DUE TO POSITIVE PREGNANCY TEST
Sep-07-2020 02:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddyr51)	Query 1: Opened	DM: The VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES, is incomplete. kindly review and complete.
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:**	Initial Entry

2.a Symptom:

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FDA-CBER-2021-5683-0008160

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** FATIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** FATIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:**	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008161

2.c

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** HEA DAC HE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** HEA DAC HE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:**	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-04-2020 23:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** CHILLS	Changed Information

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008162

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Aug/21/2020	
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** CHILLS **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** YES Ongoing? NO Stop Date: Aug/22/2020	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008163

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.d Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 23:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Ongoing? NO Stop Date: Aug/21/2020	Changed Information
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Ongoing? NO Stop Date: Aug/22/2020	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** VOMITING	Initial Entry

Confidential

FDA-CBER-2021-5683-0008164

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?:	

2.e Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** DIA RR HE A **Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** DIA RR HE A **Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?:**	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008165

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.f Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:**	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008166

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.g Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** NEW OR WORSENED JOINT PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** NEW OR WORSENED JOINT PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:**	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008167

2.h Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NEW OR WORSENED JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** RE DN ESS **Were injection site reactions present on the last day the S ubject Diary was completed ?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** RE DN ESS	Initial Entry

Confidential
FDA-CBER-2021-5683-0008168
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Were injection site reactions present on the last day the Subject Diary was completed?:	

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-11-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** SWELLING **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** SWELLING **Were injection site reactions present on the last day the Subject Diary was completed?:**	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008169

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-11-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE **Were injection site reactions present on the last day the Subject Diary was completed?:**	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008170

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 23:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-11-2020 12:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008171

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-04-2020 23:13:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/4/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-04-2020 23:13:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 98.5 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-04-2020 23:13:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-04-2020 23:13:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 98.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-04-2020 23:13:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-04-2020 23:13:50 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** ORAL CAVITY	Initial Entry

Confidential

FDA-CBER-2021-5683-0008172

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(US & Canada)		(pfe.lmartinez1)		

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008173

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/4/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113	Initial Entry

Confidential

FDA-CBER-2021-5683-0008174

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Result:: POSITIVE **Not Done::**	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-09-2020 03:21:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 2: Closed	Response satisfies query
Sep-08-2020 21:51:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	please note that subject pregnant test was negative at V1 therefore subject was vaccinated at V1. However at V2 subject was found to have a positive pregnancy test. V2 vaccine was not administered
Sep-07-2020 05:34:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 2: Opened	PDQ: Result is POSITIVE however, Subject is Randomized. Please review and correct or confirm.
Sep-07-2020 04:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Closed	Vac is marked NA.
Sep-04-2020 23:16:02 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	Query 1: Answered	correct as entered

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008175

Header Text: c4591001
Visit: V2_VAX2_L
Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:27
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

(US & Canada)		(pfe.lmartinez1)		
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Lab result is "Positive", but subject has been vaccinated. Please review and update as appropriate. Else explain.
Sep-04-2020 23:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** POSITIVE	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008176

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-04-2020 22:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-04-2020 22:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-04-2020 22:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-04-2020 22:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-04-2020 22:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-04-2020 22:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP9689	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 22:51:23	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0008177

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(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BP9689	

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Confidential
FDA-CBER-2021-5683-0008178

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-13-2020 03:27:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 1: Closed	Response satisfies query
Sep-11-2020 12:01:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	this has been updated
Sep-10-2020 03:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Reissued:Opened	DM1: Thank you for clarification. Kindly provide a form level comment of the same.
Sep-09-2020 09:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	NOT VACCINATED DUE TO POSITIVE PREGNANCY TEST
Sep-07-2020 02:49:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4622480;Temp Delay is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2. Treatment Name

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008179

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 19:53:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_EC001_2_14
Sep-16-2020 13:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	Changed data per query
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-15-2020 04:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Reissued:Opened	DM3: Form level comment appears for this form is still blank. Please consider updating NA for this form using the comment bubble data on top right corner of the

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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				form.
Sep-14-2020 10:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	EOT has been completed
Sep-13-2020 03:29:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 1: Reissued:Opened	DM2: Thank you for your response, Form level comment appears to be blank. Please consider updating the same.
Sep-11-2020 12:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	this has been updated
Sep-10-2020 03:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Reissued:Opened	DM1: Thank you for clarification. Kindly provide a form level comment of the same.
Sep-09-2020 09:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	NOT VACCINATED DUE TO POSITIVE PREGNANCY TEST
Sep-07-2020 02:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4622482;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** Not Done	Initial Entry

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(US & Canada)		(pfe.gobeidat)		
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008182

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-16-2020 13:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Done	Initial Entry
Sep-04-2020 23:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008183

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 08:51:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Oct-12-2020 09:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	Query 1: Answered	Data is not in subject record
Oct-12-2020 05:04:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4941292;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A Please review for duplication and update as appropriate.
Oct-09-2020 18:13:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry :** Oct/8/2020	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008184

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 16:36:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:07:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	Changed data per query
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-12-2020 15:00:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please complete this CRF.

2.a

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** Not Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008185

2.b

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** Not Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** Not Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008186

2.c Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** Not Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Symptom::** Not	Initial Entry

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008187

(US & Canada)		(pfe.lmartinez1)	Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	

2.e Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** Not Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008188

2.f Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptom::** Not Applicable **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Symptom::** Not	Initial Entry

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(US & Canada)		(pfe.lmartinez1)	Appli cable **Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?:** Not Appli cable	

2.h Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** Not Appli cable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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			Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable	

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** Not Applicable **Were injection site reactions present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008191

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Injection Site Reaction::** Not Applicable **Were injection site reactions present on the last day the Subject Diary was completed?:** Not Applicable	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 15:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008192

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 18:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 18:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 18:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 18:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 18:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 18:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR851V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008193

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Oct-09-2020 18:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR851V	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH40R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH40R	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH40S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH40S	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008194

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 03:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 3: Closed	Response satisfies query
Oct-12-2020 15:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	correct as is, subject completed V3 but also had a COVID illness visit done where a swab was taken
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-12-2020 05:04:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Opened	DMW4941291;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-10-2020 06:03:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-09-2020 19:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 19:39:07	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Can	Date of Visit is completed but Date of Assessment in the

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(UTC-06:00) Central Time (US & Canada)			didate	Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-09-2020 19:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Can didate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-09-2020 19:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry :** Oct/8/ 2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-09-2020 19:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** COVID_A	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008196

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/8/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/5/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO Date of Last Symptom Resolved: Oct/7/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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4.b

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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4.d

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom P resent:** NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.f

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090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW LOSS OF TASTE OR SMELL **Symptom Present:** NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** YES	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008200

4.h

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-12-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008201

Oct-12-2020 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms - Other:** Nasal congestion	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-12-2020 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Nasal congestion	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 10:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms - Other:** Intermittent headaches	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-12-2020 10:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Intermittent headaches	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008202

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-14-2020 07:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Oct-13-2020 14:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	Changed data per query
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-13-2020 10:14:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Opened	CLIQUERY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

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4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008204

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-13-2020 14:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008205

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-18-2020 07:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Imran Abdul Salam Kazi (pfe kazii)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	Comment "not done due to site collecting swab in office" is noted on page. History of queries also provide the answer to your question. Site was guided enter not done. Why is this being queried?
Oct-16-2020 01:42:15 (UTC-06:00) Central Time	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Reissued:Opened	DM2: 'Sample Collected?' is marked as No Done and 'If no sample was collected

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(US & Canada)				or sample was not collected according to protocol, please provide reason' is missing. Please update the reason at the appropriate section of the crf question#4.
Oct-15-2020 09:24:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	Changed data per query
Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry :** Not Done	Initial Entry
Oct-15-2020 03:38:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Reissued:Opened	DM1: Per site response, If only in clinic swab type is taken, self swab form that is not used should have “Sample Collected” as NO and the reason documented.' Kindly review and update.
Oct-14-2020 09:39:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	NA due to swab completed in clinic
Oct-14-2020 02:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Reissued:Opened	DM: Per CCG, If only one swab type is taken, The other form that is not used should have “Sample Collected” as NO and the reason documented.' Kindly review and update.
Oct-13-2020 14:45:35 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	Original value is correct

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(US & Canada)				
Oct-13-2020 00:56:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4954365;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-15-2020 09:23:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-12-2020 15:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

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FDA-CBER-2021-5683-0008208

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 19:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 19:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 19:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 19:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 19:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection: Oct/8/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-17-2021 10:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 1: Closed	Response satisfies query
Feb-12-2021 15:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	PLEASE UNLOCK MEDICAL HISTORY PAGE TO ADD IRREGULAR

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				MENSTRUAL CYCLES AND SPONTANEOUS MISCARRIAGE REPORTED
Feb-12-2021 14:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 1: Opened	Patient 10961031, med history, source indicates "Irregular Menstrual Cycles" and "Spontaneous Miscarriage" that are not in edc. Please consider reviewing and adding to EDC MH Form. Will unlock for entry.

5.a

Date	Location	User	Value	Reason
Oct-09-2020 19:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR851R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 19:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR851R	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:** NO	Initial Entry

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FDA-CBER-2021-5683-0008211

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:** NO	Initial Entry

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FDA-CBER-2021-5683-0008212
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:** NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:** NO	Initial Entry

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090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-12-2020 10:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

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FDA-CBER-2021-5683-0008214

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 10:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008215

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-13-2020 14:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry
Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-13-2020 21:14:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_CEIDT008_01
Oct-13-2020 14:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-13-2020 14:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-13-2020 01:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4951166;Was a diagnosis obtained for Potential COVID-19 Illness? is not expected to be

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				Unknown or Not Applicable. Please review and update appropriately or clarify
Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 02:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Closed	Data updated
Oct-15-2020 09:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-15-2020 09:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 1	Initial Entry
Oct-15-2020 09:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:**	Initial Entry
Oct-15-2020 04:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Reissued:Opened	DM1: Unknown or Not applicable is not acceptable as symptoms are reported on SOD form. Per CRF CRs Section 8.30.5, please enter worst toxicity grade (1 to 5), please review and update as appropriate.
Oct-14-2020 09:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	no diagnosis made therefore NA
Oct-14-2020 02:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	DM: Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it

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FDA-CBER-2021-5683-0008217

				relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Oct-13-2020 14:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-13-2020 14:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-12-2020 10:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008218

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 10:11:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008219

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008220

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008221

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential
FDA-CBER-2021-5683-0008222
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008223

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008224

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008225

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential
FDA-CBER-2021-5683-0008226
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008227

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008228

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008229

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008230

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008231

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential
FDA-CBER-2021-5683-0008232
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008233

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008234

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008235

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential
FDA-CBER-2021-5683-0008236
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008237

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008238

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008239

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential
FDA-CBER-2021-5683-0008240
090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008241

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0008242

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

			Result:: Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-12-2020 10:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008243

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Record Identifier::** Not Applicable **Systolic::** Not Applicable **Diastolic::** Not Applicable **Respiratory Rate in respirations/minute:** Not Applicable **Heart Rate in beats/minute:** Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008244

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008245

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Record Identifier::** Not Applicable **Oxygen Saturation:** Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-12-2020 10:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008246

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-12-2020 10:14:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008247

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 10:14:43 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008248

(US & Canada)				

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008249

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/08/2020 | **Form:** IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-12-2020 10:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008250

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/05/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 09:44:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Nov/5/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-06-2020 09:44:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COVID_A1	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008251

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/05/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Nov-06-2020 09:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 09:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-06-2020 09:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 09:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 09:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-06-2020 09:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR98YD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 09:44:50	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0008252

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/05/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BR98YD	

5.b

Date	Location	User	Value	Reason
Nov-06-2020 09:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH43T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 09:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH43T	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-06-2020 09:45:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH43V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 09:45:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH43V	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008253

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-14-2020 10:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-14-2020 10:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-14-2020 10:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** PREGNANCY	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008254

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Sep-30-2020 08:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Deleted	Transcription Error
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Form Created	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008255

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Form Created	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008256

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Jan-07-2021 18:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Form Deleted	Transcription Error
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	Form Created	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008257

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	Form Created	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008258

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Oct-13-2020 16:01:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Deleted	New Information
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	Form Created	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008259

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008260

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-01-2020 05:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Closed	data deleted.
Sep-30-2020 08:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-27-2020 02:51:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Reissued:Opened	DM2: Form has been unfrozen. Please consider making the necessary changes, Thank you.
Sep-26-2020 09:23:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	Can this be unfroze to delete entry?
Sep-24-2020 01:15:56 (UTC-06:00)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued:Opened	DM 1: As per CRF Completion

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008261

***** THIS REPEATING FORM HAS BEEN DELETED *****

Central Time (US & Canada)				Requirements and Protocol, eDiary events do not need to be captured on the AE form. Please review and update. Else, clarify
Sep-23-2020 11:20:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	this was ongoing on day 7 and therefore needs to be added-please confirm
Sep-17-2020 03:39:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Reissued:Opened	DM: As per CRF Completion Requirements and Protocol, eDiary events do not need to be captured on the AE form. Kindly review and update.
Sep-16-2020 13:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	Original value is correct
Sep-14-2020 01:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	eDiary: AE Chills reported with start date 20-Aug-2020 and End Date 21-Aug-2020 seems to be same as e-Diary occurrence Chills reported on 20-Aug-2020. Please reconcile or confirm in the query

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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***** THIS REPEATING FORM HAS BEEN DELETED *****

				response as appropriate. "[naikp09 SDQ=6854]"
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** CHILLS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date Time: Aug/21/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-04-2020 23:38:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008263

***** THIS REPEATING FORM HAS BEEN DELETED *****

Sep-04-2020 23:38:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-04-2020 23:38:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Changed Information
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE CHILLS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

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090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

***** THIS REPEATING FORM HAS BEEN DELETED *****

			NO Is this serious event life threatenin g? NO Other medically important serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER *If Other, specify:* PREGNANCY	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** NO	Initial Entry

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FDA-CBER-2021-5683-0008265

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

(US & Canada)		(pfe.lmartinez1)		

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-04-2020 23:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-04-2020 23:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** RECOVERED/RESOLVED	Changed Information
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE CHILLS: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-04-2020 23:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008266

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 21:58:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Nov-05-2020 18:08:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-05-2020 18:08:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** EXPOSURE DURING PREGNANCY	New Information
Nov-03-2020 07:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020345020, the term was reported as pregnancy. Based on the latest EDP guidance,term should be reported as 'EXPOSURE DURING PREGNANCY. Please confirm and update accordingly
Sep-09-2020 06:40:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	reported under AER 2020345020
Sep-08-2020 20:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	THIS IS A SAE-PLEASE CLARIFY WHICH FORM IS IT MISSING FROM

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008267

Sep-07-2020 04:54:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: PREGNANCY(Onset date:04Sep2020) is not reported on SAE Report Form but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** PREGNANCY	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-13-2020 14:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 13: Closed	Response satisfies query
Nov-13-2020 14:49:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 12: Closed	Response satisfies query
Nov-13-2020 12:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 13: Answered	Time was updated to UNK:UNK per DM query, as conception occurred prior to vaccination 1.
Nov-13-2020 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 13: Opened	For AE EXPOSURE DURING PREGNANCY: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Nov-13-2020 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 12: Answered	Data updated per query
Nov-13-2020 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/14/2020 UNK:UNK	Data updated per query
Nov-13-2020 08:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 12: Reissued:Opened	As per completion guidelines version 10.0, If conception occurred prior to vaccination 1, time to be

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				recorded as UNK:UNK. Please review and update as appropriate. Else clarify.
Nov-12-2020 16:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 12: Answered	Changed data per query
Nov-12-2020 03:53:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 12: Opened	As per completion guidelines version 10.0, If conception occurred prior to vaccination 1, time to be recorded as UNK:UNK. Please review and update as appropriate. Else clarify.
Oct-30-2020 05:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 10: Closed	Response satisfies query
Oct-29-2020 18:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 11: Closed	Close Auto Query
Oct-29-2020 18:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/14/2020 18:11	Transcription Error
Oct-29-2020 18:07:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 11: Opened	For AE PREGNANCY: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Oct-29-2020 18:07:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 10: Answered	Transcription Error
Oct-29-2020 18:07:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/14/2020 UNK:UNK	Transcription Error
Oct-29-2020 04:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 10: Opened	SAE RECON:AER#2020345020, as exposure to pregnancy can only occur at the time of vaccination onset date should reflect the date of vaccination. The date of vaccination is 14Aug2020. Please confirm and update as appropriate.

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Oct-17-2020 08:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Onset date updated in SDB to 09Aug2020. Issue resolved
Oct-15-2020 08:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 7: Closed	Response satisfies query
Oct-14-2020 09:32:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 7: Answered	Correct as is. Pregnancy was not confirmed until after consent date. Start date is an estimate start date based on ultrasound.
Oct-14-2020 03:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 7: Reissued:Opened	DM1: Thank you for the response. However, as the Start date is prior to the consent date, this event should be reported on Medical history page. Please update as appropriate or else clarify.
Oct-12-2020 20:43:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	Per email follow up AEM form faxed. Pending SDB update
Oct-12-2020 15:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	data is present for both onset date and resolution date
Oct-12-2020 15:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 7: Answered	data is entered correctly, date of onset is listed and resolution date is also listed. Per sponsor this is to be listed as an AE not medical history
Oct-12-2020 04:36:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 5:Per latest SAE listing the onset date of AER 2020345020 is still missing/not reported. Please submit a follow up AEM form to report the correct onset date of event to Safety database.
Oct-10-2020 06:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 6: Closed	Another query placed
Oct-10-2020 06:56:39 (UTC-06:00) Central	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 7: Reissued:Opened	DM: As the Start date is prior to the consent date,

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Time (US & Canada)				kindly review and confirm if this event should be reported on Medical history page?, thank you.
Oct-10-2020 06:54:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 8: Closed	Another query placed
Oct-10-2020 06:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 9: Closed	Another query placed
Oct-09-2020 05:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	For Clinical review
Oct-08-2020 09:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 8: Answered	this is correct
Oct-08-2020 09:01:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 9: Answered	updated
Oct-08-2020 09:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Opened	For PREGNANCY: Start date 09/Aug/2020 is before V1D1VX1L visit date 14/Aug/2020. Please review and update as appropriate.
Oct-08-2020 09:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Opened	Start date is before Consent Date 14/Aug/2020.
Oct-08-2020 09:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-08-2020 09:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/9/2020 UNK:UNK	Changed Information
Oct-07-2020 05:05:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 4: Per latest SAE listing the onset date of AER 2020345020 is still missing/not reported. Please submit a follow up AEM form to report the correct onset date of event to Safety database.
Oct-06-2020 20:20:19 (UTC-06:00) Central	ACV0PFEINFP6000	Lizatte Martinez	Query 7: Answered	correct as entered

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Time (US & Canada)		(pfe.lmartinez1)		
Oct-06-2020 20:20:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 6: Answered	correct as entered
Oct-06-2020 20:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Opened	For PREGNANCY: Start date 07/Aug/2020 is before V1D1VX1L visit date 14/Aug/2020. Please review and update as appropriate.
Oct-06-2020 20:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Start date is before Consent Date 14/Aug/2020.

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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 20:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-06-2020 20:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/7/2020 UNK:UNK	Changed Information
Oct-01-2020 09:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 4: Closed	Another related query is already open.
Oct-01-2020 09:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 5: Closed	Related another SAE recon query already present.
Sep-30-2020 23:10:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 3: The onset date was updated to 09Aug2020. Please confirm if a follow up AEM form was sent to indicate the correct onset date of event to Pfizer Safety.
Sep-30-2020 23:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	For Clinical review
Sep-30-2020 13:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 4: Answered	confirmed with sponsor the AE is correctly noted because subj was exposed to IP before AE was confirmed.
Sep-30-2020 13:10:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 4: Reissued:Opened	Please note that as the AE start date of 9/Aug/2020 is before the Consent date of 14/Aug/2020, the AE should be recorded on the Medical History page.
Sep-30-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 4: Answered	Original value is correct

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Sep-30-2020 08:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 5: Answered	Changed data per query
Sep-30-2020 08:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	For PREGNANCY: Start date 09/Aug/2020 is before V1D1VX1L visit date 14/Aug/2020. Please review and update as appropriate.
Sep-30-2020 08:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Start date is before Consent Date 14/Aug /2020.
Sep-30-2020 08:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-30-2020 08:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Aug/9/2020 UNK:UNK	New Information
Sep-29-2020 05:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 2:Per Clinical comment "gestational age 6 weeks 2 days by 22/Sep/2020, and probable date of conception by ultrasound is 09/Aug /2020.The ultrasound is the more accurate way to date a pregnancy, date of onset should be 09/Aug/2020." Please confirm
Sep-24-2020 04:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	SAE RECON: For Clinical review
Sep-23-2020 23:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 3: Closed	Response satisfies query
Sep-23-2020 23:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Closed	Response satisfies query
Sep-23-2020 11:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	confirmed

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Sep-23-2020 11:25:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	coonfirmed
Sep-23-2020 11:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For PREGNANCY: Start date 07/Aug/2020 is before V1D1VX1L visit date 14/Aug/2020. Please review and update as appropriate.
Sep-23-2020 11:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Start date is before Consent Date 14/Aug /2020.
Sep-23-2020 11:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	date was updated per gestational age given to subject
Sep-23-2020 11:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/7/2020 UNK:UNK	date was updated per gestational age given to subject
Sep-17-2020 09:49:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Reissued:Opened	SAE RECON 1: Per latest SAE listing from Safety, onset date is still blank. Please submit a follow up AEM form to update onset date in Safety database.
Sep-16-2020 13:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	Original value is correct
Sep-16-2020 07:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020345020,onset date was reported as 04Sep2020 while blank in Safety. Per PSSR 'There was no event onset date provided in the source document.Please submit follow up AEM form to provide onset date.
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/4/2020 15:58	Initial Entry

5. Is the adverse event still ongoing?

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Nov-09-2020 12:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-09-2020 12:14:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	are you asking on the SAE report that was submitted? If so this information was already submitted with an end date
Nov-09-2020 01:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 2: Opened	CLINICAL - please submit the End date for this event (ie elective termination date) in a safety update, in the Event section 'End date' box
Nov-08-2020 12:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Candidate	CLINICAL - please submit the End date for this event (ie elective termination date) in a safety update, in the Event section 'End date' box
Nov-08-2020 12:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	reopen as candidate query
Nov-08-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - please submit the End date for this event (elective termination date) in a safety update, in the event section 'end date' box
Sep-23-2020 11:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date Time: Sep/22/2020 UNK:UNK	New Information
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

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Date	Location	User	Value	Reason
Nov-13-2020 04:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 1: Closed	Response satisfies query
Nov-12-2020 16:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Nov-12-2020 16:07:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-12-2020 16:07:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Nov-12-2020 03:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Toxicity grade is not expected for pregnancy related adverse events, hence please remove the toxicity and add item level comment as NOT APPLICABLE.
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-12-2020 07:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Closed	Seriousness downgraded to NO in Inform. Issue resolved
Oct-12-2020 04:37:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Oct-09-2020 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE PREGNANCY: Response to "Is the adverse event

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				serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-09-2020 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	New Information
Oct-06-2020 20:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	in the opinion of the PI this even was severe
Oct-01-2020 16:21:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Reissued:Opened	Thank you for your answer. Could you please elaborate on how this event mets seriousness criteria?
Sep-30-2020 08:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 2: Answered	Original value is correct
Sep-29-2020 08:47:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Opened	The pregnancy was appropriately reported to safety; however, seriousness criteria is met only if there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-07-2020 04:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	not yet reported in SDB. to update field once avaialable
Sep-07-2020 04:48:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Opened	DM: For AE PREGNANCY: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. Thank you.
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE PREGNANCY: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Is this serious event associated wi th congenital anomaly or birth def ect? NO Did this serious event result in de ath? NO Did this serious event require or p rolong hospitalization? NO	Initial Entry

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			Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* PREGNANCY	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-13-2020 05:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	SDB action taken updated
Nov-12-2020 05:51:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Reissued:Candidate	to check next SAE listing

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Nov-11-2020 15:21:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 2: Answered	Subject was safely withdrawn from vaccine #2 due to positive pregnancy test , SAE performed.
Nov-11-2020 04:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020345020,action taken was reported as DRUG WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm. If safety update is required, please submit a follow up form
Nov-06-2020 04:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Nov-05-2020 18:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-05-2020 18:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** DRUG WITHDRAWN	Transcription Error
Nov-04-2020 06:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: EOT tab has been completed to indicate drug was withdrawn due to pregnancy. However, this field 'Last Action Taken with Study Treatment' indicates Not Applicable. Please review to reconcile the entries
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-23-2020 11:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 11:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** RECOVERED/RESOLVED	New Information
Sep-23-2020 11:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE PREGNANCY: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-04-2020 23:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-12-2020 04:37:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:**	event downgraded to non serious
Sep-09-2020 06:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020345020	Initial Entry

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FDA-CBER-2021-5683-0008282

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-08-2021 13:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 2: Closed	data moved to COV ILL eCRF
Jan-07-2021 18:53:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 2: Answered	will remove from AE log
Jan-04-2021 16:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 2: Opened	GPD Clin: Per protocol 8.3.7. symptoms that could be attributed to a Pot COVID-19 ILL don't qualify as AE and should be documented on the COVID-19 CRF ILLNESS DETAILS form ONLY and should not be captured on the AE CRF page. Please update accordingly
Jan-01-2021 15:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query

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Dec-28-2020 16:41:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	Please clarify query. Last update sent captures recovery date 22-SEP-2020. Line #11 and 12 do have a section for end date. Also, SAE report is 2020345020. Please clarify and confirm subject number.
Dec-22-2020 10:13:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Please submit a SAE safety update (#202040361) reporting the end date of event Exposure during Pregnancy, in the Event section of the report
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Nasal congestion	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-04-2021 09:08:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 2: Closed	Response satisfies query
Dec-28-2020 16:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	data updated
Dec-28-2020 16:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO End Date Time: Oct/10/2020 UNK:UNK	data updated
Dec-21-2020 11:47:51	ACV0PFEINFP6000	Karin Kolbe	Query 2: Opened	CLINQUERY: Please

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(UTC-06:00) Central Time (US & Canada)		(pfe kolbek01)		determine if this AE is ONGOING. Please update or confirm.
Oct-14-2020 14:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-14-2020 13:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	correct as is
Oct-14-2020 09:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please determine if this AE is ONGOING. Please update or confirm.
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008285

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Personal illness	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-28-2020 16:41:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-28-2020 16:41:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** RECOVERED/RESOLVED	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Dec-28-2020 16:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Nasal congestion: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-12-2020 09:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

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FDA-CBER-2021-5683-0008287

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Sore throat	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO End Date Time: Oct/7/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** 1	Initial Entry

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER *If Other, specify:* Personal illness	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-12-2020 09:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 08:50:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Oct-13-2020 16:01:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-13-2020 01:34:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	The AE Intermittent headaches was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE

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***** THIS REPEATING FORM HAS BEEN DELETED *****

				as baseline conditions should only be reported as AEs if they worsen. "[malipn01 SDQ=17669]"
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Intermittent he adaches	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 10:01:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** NO End Date Time: Oct/6/2020 UNK:UNK	New Information
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** NO	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require

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***** THIS REPEATING FORM HAS BEEN DELETED *****

medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER *If Other, specify:* Personal illness	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008293

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted, Frozen
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-12-2020 10:01:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Intermittent headaches: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-12-2020 10:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008294

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-03-2021 11:57:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Closed	Response satisfies query
Feb-02-2021 15:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	pathogen is not known
Feb-02-2021 07:20:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Opened	GPD Clin: Can you please confirm, if pathogen causing urinary tract infection is known? Please review and update AE term as needed. Thanks
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** urinary tract infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/22/2021 UNK:UNK	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* unknown	Initial Entry

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FDA-CBER-2021-5683-0008296

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961031
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-01-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008297

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Jan/27/2021	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008298

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-27-2021 15:50:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/27/2021	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008299

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Jan-27-2021 16:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-27-2021 16:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-27-2021 16:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 16:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-27-2021 16:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Date of Collection: Jan/27/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-27-2021 16:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Sample ID:** BSH4FC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 16:50:31	ACV0PFEINFP6000	Rocio	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0008300

(UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe.rgutierrez)	BSH4FC	

5.b

Date	Location	User	Value	Reason
Jan-27-2021 16:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Sample ID:** BSH4FB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 16:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** BSH4FB	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-27-2021 16:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Sample ID:** BR85K4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 16:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** BR85K4	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008301

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Jan-27-2021 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-27-2021 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-27-2021 16:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-27-2021 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Date of Collection: Jan/27/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-27-2021 16:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Sample ID:** BR85K9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 16:51:03	ACV0PFEINFP6000	Rocio	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0008302

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe.rgutierrez)	BR85K9	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008303

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled Visit on Feb/10/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 11:35:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/10/2021	Transcription Error
Feb-11-2021 15:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/11/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Feb-11-2021 15:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** SSWAB_WEEK2	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008304

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled Visit on Feb/10/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 15:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 15:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 05:42:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Feb-12-2021 11:35:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Feb-12-2021 09:21:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katerina Trpeski (pfe.TRPESK)	Query 2: Reissued:Opened	DM Q: The actual visit starts when the first assessment was performed and in this case it was on 10Feb2021(Repeat Swab). Please review and update as appropriate.
Feb-11-2021 15:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 15:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 2: Answered	swab received today
Feb-11-2021 15:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection is different from Date of Visit. Please review

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008305

				and update as appropriate, else clarify.
Feb-11-2021 15:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 15:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 15:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Sample ID:** AA10766	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 15:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** AA10766	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 - Unscheduled Visit on Feb/24/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 15:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/24/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Feb-24-2021 15:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** SSWAB_WEEK4	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008307

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 - Unscheduled Visit on Feb/24/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Feb-24-2021 15:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-24-2021 15:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 15:46:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 15:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 15:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Date of Collection: Feb/24/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 15:46:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Sample ID:** AA10753	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 15:46:39	ACV0PFEINFP6000	Rocio	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0008308

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe.rgutierrez)	AA10753	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008309

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 18:18:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Mar/1/2021	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008310

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-02-2021 18:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 18:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-02-2021 18:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008311

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-02-2021 18:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Mar/1/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-02-2021 18:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008312

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 13:49:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Mar/3/2021	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008313

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Mar-04-2021 13:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** OBTAINED Date Written Consent Obtained Mar/3/2021	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008314

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961031

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-04-2021 13:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Mar/3/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-04-2021 13:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-04-2021 13:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008315

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-10-2021 00:38:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pankaj Bhoir (pfe.bhoirp02)	Query 1: Closed	Response satisfies query
Mar-09-2021 11:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	corrected
Mar-09-2021 11:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/3/2021	corrected
Mar-07-2021 23:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	PDQ: Date of the pregnancy test (4/Mar /2021) does not the same day as the vaccination (3/Mar /2021). Please review and correct or confirm.
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Mar/4/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008316

(US & Canada)				

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done::**	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-04-2021 13:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEGATIVE	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008317

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 08:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 08:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 08:55:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 08:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 08:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 08:55:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNPY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 08:55:52	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0008318

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BNZNPY	

5.b

Date	Location	User	Value	Reason
Mar-05-2021 08:56:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNVTNF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 08:56:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNVTNF	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-05-2021 08:56:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNVTNG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 08:56:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNVTNG	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008319

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 08:56:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 08:56:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 08:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 08:56:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 08:56:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 08:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNR0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 08:57:15	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0008320

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BNZNR0	

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008321

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Mar/3/2021 11:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** LEFT	Initial Entry

7. Route:

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008322

Header Text: c4591001
Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961031 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-04-2021 14:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008323

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Sep-14-2020 10:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DISCONTINUED	Initial Entry
Aug-18-2020 09:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-14-2020 21:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-14-2020 10:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/4/2020	Initial Entry
Aug-18-2020 09:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/14/2020	Initial Entry
Aug-14-2020 21:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/14/2020	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008324

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961031 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 17:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae308f\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008325

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008326

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008327

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961036]
2.	Birth Date:	(b) (6)/1988
3.	Sex:	FEMALE
4.	Ethnicity:	NOT REPORTED
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008328

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/17/2020
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008329

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008330

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation/Death	Aug/17/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008331

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bipolar disorder]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fatty Liver Disease]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008332

1.e

Line/MH Number:	[5]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
Start Date:	UNK/UNK/2017
Ongoing:	YES

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008333

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/17/2020
2.	Weight:	[231.0]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[35.1]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008334

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Lab Urinalysis		
1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/17/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008335

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/17/2020
2.	Randomization Number:	[51014]
3.	Randomization Group:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008336

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DVF]
5.b	Sample ID	[BP5DVG]
5.c	Sample ID	[BP5DVH]
5.d	Sample ID	[BPRHX6]
5.e	Sample ID	[BPRHX7]

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FDA-CBER-2021-5683-0008337

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DV6]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008338

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/17/2020 16:22
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008339

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008340

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008341

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/9/2020

Vital Signs Details		
2.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008342

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Lab Urinalysis		
1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008343

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5FB0]

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FDA-CBER-2021-5683-0008344

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 15:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008345

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008346

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR850R]
5.b	Sample ID	[BSH3ZC]
5.c	Sample ID	[BSH3ZD]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008347

Header Text: c4591001	
Visit: V4_MONTH6_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008348

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008349

Header Text: c4591001	
Visit: V5_MONTH12_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008350

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008351

Header Text: c4591001	
Visit: V6_MONTH24_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008352

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008353

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008354

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008355

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008356

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008357

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** HEALTH CARE UTILIZATION
Form Version: 20-Feb-2021 02:19	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008358

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

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FDA-CBER-2021-5683-0008359

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008360

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008361

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008362

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008363

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008364

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008365

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** DATE OF VISIT - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008366

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008367

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961036 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	worsening of depression with suicidal ideation	Oct/UNK/2020 UNK:UNK	NO End Date Time: Nov/14/2020 UNK:UNK	Repeating Pages

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008368

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Queries

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening of depression with suicidal ideation]
4.	Start Date Time:	Oct/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/14/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008369

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Queries

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [depression]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021230302]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008370

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961036 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008371

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008372

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Nov/1/2020	Repeating Pages

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008373

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Nov/1/2020

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008374

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961036 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008375

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008376

Header Text: c4591001
Visit: Logs **Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961036 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008377

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008378

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008379

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008380

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008381

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008382

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Lab Urinalysis		
1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	
Lab Result		
6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008383

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008384

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008385

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008386

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008387

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008388

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008389

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008390

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008391

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008392

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Feb/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008393

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008394

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008395

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/2/2021
2.	Erroneous Visit	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008396

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/2/2021

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008397

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Inclusion Criteria Not Met		
1.a	Description of Inclusion Criterion Not Met	Healthy participants, determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for the study. Specific criteria apply for HIV/HCV/HBV
Exclusion Criteria Met		
2.a	Description of Exclusion Criterion Met	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008398

Header Text: c4591001

Visit: V101_VAX3 **Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31 **Form Status:** Data Complete, Queries, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death:	Not Done //	Comments
2.	Phase of Disposition:	Not Done	Comments
3.	Status:	Not Done	Comments
4.	Specify Status:	Not Done [ ]	Comments

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008399

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008400

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961036	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008401

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 18:31:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008402

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Aug-17-2020 20:18:44 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008403

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Queries, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done
Form	Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008404

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Queries, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done
1	Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008405

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Queries, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done
2	Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008406

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Queries, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done
3	Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008407

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Queries, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
4	Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done
4	Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008408

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 18:31:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Mar-09-2021 17:45:55 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Mar-09-2021 13:10:05 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Feb-23-2021 15:33:32 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008409

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Van Tran	Approved	Feb-22-2021 14:31:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rene Saenz	N/A	Nov-19-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Oct-23-2020 19:11:12 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008410

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-17-2020 20:17:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-17-2020 20:17:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008411

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-17-2020 20:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008412

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-17-2020 20:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961036	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1988	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 20:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 20:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT REPORTED	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-17-2020 20:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** WHITE	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008413

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 20:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/17/2020	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008414

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-17-2020 20:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 20:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 20:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008415

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-17-2020 20:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** bipolar disorder **Start Date:** UNK/UNK/2004 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** bipolar disorder	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** UNK/UNK/2004	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008416

1.b

Date	Location	User	Value	Reason
Aug-17-2020 20:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Anxiety **Start Date:** UNK/UNK/2004 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Anxiety	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** UNK/UNK/2004	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

1.c

Confidential
FDA-CBER-2021-5683-0008417
090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961036
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-17-2020 20:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number :** 3 **Medical History Term:** depression **Start Date:** UNK/UNK/2004 **Ongoing:** YES	Initial Entry

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** depression	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** UNK/UNK/2004	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 20:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008418

Aug-17-2020 20:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** Fatty Liver Disease **Start Date:** UNK/UNK/2019 **Ongoing:** YES	Initial Entry

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 20:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 20:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Fatty Liver Disease	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** UNK/UNK/2019	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 20:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-19-2020 10:06:40 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number** 5	Initial Entry

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FDA-CBER-2021-5683-0008419
090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)			**:** **Medical History Term:** Obesity **Start Date:** UNK/UNK/2017 **Ongoing:** YES	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Nov-19-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-19-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Obesity	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Nov-19-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Nov-19-2020 10:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** YES	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008420

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 231.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 68.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 35.1	Initial Entry

Confidential

FDA-CBER-2021-5683-0008421

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)				

7.a

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 98.7 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 98.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008422

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008423

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done::**	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-17-2020 20:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEGATIVE	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008424

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-17-2020 20:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 20:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 51014	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008425

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 20:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 20:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 20:34:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 20:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 20:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 20:34:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DVF	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008426

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 20:34:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DVF	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 20:34:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DVG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 20:34:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DVG	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-17-2020 20:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DVH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 20:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DVH	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHX6	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008427

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHX6	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-17-2020 20:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHX7	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 20:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHX7	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008428

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 20:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 20:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 20:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 20:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DV6	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008429

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 20:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DV6	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008430

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961036
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Aug/17/2020 16:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:** LEFT	Initial Entry

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FDA-CBER-2021-5683-0008431

Time (US & Canada)		(pfe rgutierrez)		

7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-17-2020 20:31:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008432

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-17-2020 20:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008433

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 10:41:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008434

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 10:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier ::** 1 **Temperature:** 99.0 **Temperature Unit :** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 99.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** F	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008435

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008436

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008437

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done::**	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NEGATIVE	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008438

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 10:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 10:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 19:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 10:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 10:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 19:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5FB0	Initial Entry

Confidential

FDA-CBER-2021-5683-0008439

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 19:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5FB0	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008440

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961036
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020 15:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** LEFT	Initial Entry

Confidential
FDA-CBER-2021-5683-0008441

Time (US & Canada)		(pfe.gobeidat)		

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-10-2020 10:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008442

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 15:17:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/7/2020	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008443

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 15:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 15:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR850R	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008444

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR850R	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 12:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZC	Transcription Error
Oct-08-2020 15:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZD	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008445

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 20:51:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-09-2020 12:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-09-2020 12:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZC	Transcription Error
Oct-08-2020 20:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4929464;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-08-2020 15:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZD	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 15:18:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZD	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008446

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 07:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Closed	Relevant query present
Oct-08-2020 20:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4929465;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-08-2020 15:18:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZD	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008447

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-08-2020 18:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-08-2020 18:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-08-2020 18:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008448

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008449

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Queries

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 14:41:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	typo
Mar-05-2021 14:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - p
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** worsening of depression with sui cidal ideation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 17:46:08 (UTC-06:00) Central	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** NO	Transcription Error

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008450

Time (US & Canada)		(pfe.ydavila)	End Date Time: Nov/14/2020 UNK:UNK	
Mar-09-2021 17:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date Time: Nov/12/2020 UNK:UNK	Transcription Error
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date Time: Nov/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-04-2021 03:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE worsening of depression with suicidal ideation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008451

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961036
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008452

Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatmen t(s), this event is due to: OTHER *If Other, specify:* depression	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-10-2021 15:35:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 3: Opened	Since this subject had already completed VAX1 and VAX2 prior to this AE start and stop date; the Action Taken with study drug cannot be drug withdrawn and should be updated to Not Applicable. Please update else clarify.
Mar-08-2021 00:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candi date	Pending SDB update
Mar-05-2021 20:40:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Mar-05-2021 15:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	updated in SAE form
Mar-05-2021 15:34:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 2: Answered	confirmed
Mar-05-2021 14:44:15 (UTC-06:00) Central	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - VAX3 was not administered when this SAE was reported; please

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Time (US & Canada)				confirm that the option for VAX3 is permanently withdrawn for this subject
Mar-04-2021 03:24:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021230302 ,action taken was reported as DRUG WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm. If safety update is required, please submit a follow up form
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-05-2021 20:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for requested SAE treatment information.
Mar-05-2021 15:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	will update SAE
Mar-05-2021 14:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - Medication for SAE reported as YES; please report medications received for SAE in a SAE report update
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

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090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Queries

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-03-2021 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-04-2021 03:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2021230302	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008455

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-03-2021 11:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008456

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-03-2021 11:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-03-2021 11:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-03-2021 11:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-03-2021 11:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-03-2021 11:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Nov/1/2020	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008457

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 15:33:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Feb/22/2021	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008458

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-23-2021 15:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-23-2021 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national re commendations and confir med to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008459

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-23-2021 15:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Feb/22/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 15:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008460

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 11:23:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/2/2021	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008461

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Mar-03-2021 11:24:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OBTAINED Date Written Consent Obtained Mar/2/2021	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008462

Header Text: c4591001

Visit: V101_VAX3 **Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Mar-03-2021 11:24:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Criterion Description:** Healthy participants, determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for the study. Specific criteria apply for HIV/HCV/HBV	Initial Entry

1.a Description of Inclusion Criterion Not Met

Date	Location	User	Value	Reason
Mar-03-2021 11:24:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Healthy participants, determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for the study. Specific criteria apply for HIV/HCV/HBV	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-03-2021 11:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Criterion Description:** Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Description of Exclusion Criterion Met

Date	Location	User	Value	Reason

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008463

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Mar-03-2021 11:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008464

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Queries, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961036

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-10-2021 15:37:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 2: Opened	Since this subject was re-evaluated for VAX3 and did not qualify due to INCL/EXCL not being met; please update to the date of REVAX conf and add status of No Longer meets eligibility criteria; else clarify.
Mar-09-2021 15:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_17
Mar-09-2021 11:45:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	corrected
Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry
Mar-04-2021 11:04:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7588122;Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or

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FDA-CBER-2021-5683-0008465

				clarify
Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry
Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry
Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Mar-09-2021 11:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry
Mar-03-2021 11:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008466

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-08-2020 18:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-17-2020 20:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 20:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-08-2021 00:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Mar-05-2021 15:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 2: Answered	recorded as serious in AE CRF
Mar-03-2021 09:09:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2021230302 Worsening of depression with suicidal ideationwas reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Feb-04-2021 02:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008467

Header Text: c4591001
Visit: Subject Status - Unscheduled
Form: SUBJECT STATUS - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961036
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Feb-03-2021 12:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	site has reached out to subject with multiple attempts, no response from subject in regards to eDiary report on 29JAN2021
Feb-03-2021 01:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Opened	RQ1: Thank you for the response. Please consider to follow-up and confirm for reported Illness eDiary response of 29JAN2021. Please update or clarify.
Feb-02-2021 15:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	site has been unable to contact site after multiple attempts.
Feb-02-2021 13:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 29JAN2021. But there is no COVID Illness visit reported in the database. Please clarify.
Oct-08-2020 18:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/7/2020	Initial Entry
Aug-17-2020 20:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/17/2020	Initial Entry
Aug-17-2020 20:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/17/2020	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008468

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961036 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 17:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae3095\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008469

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection		
DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.		
1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008470

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/18/2020

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008471

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961044]
2.	Birth Date:	(b) (6)/1961
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008472

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/18/2020
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008473

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008474

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation/Death	Aug/18/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008475

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIABETES MELLITUS TYPE 2]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIABETIC NEUROPATHY]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INSOMIA]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

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FDA-CBER-2021-5683-0008476

1.e

Line/MH Number:	[5]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEPRESSION]
Start Date:	UNK/UNK/2017
Ongoing:	YES

1.f

Line/MH Number:	[6]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CORONATY ARTERY DISEASE]
Start Date:	Jul/4/2017
Ongoing:	YES

1.g

Line/MH Number:	[7]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CONGESTIVE HEART FAILURE]
Start Date:	Jul/4/2017
Ongoing:	YES

1 h

Line/MH Number:	[8]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CHRONIC KIDNEY DISEASE]
Start Date:	UNK/UNK/2017
Ongoing:	YES

1.i

Line/MH Number:	[9]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SLEEP APNEA]
Start Date:	UNK/UNK/2017
Ongoing:	YES

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FDA-CBER-2021-5683-0008477

1.j

Line/MH Number:	[10]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ANXIETY]
Start Date:	UNK/UNK/2017
Ongoing:	YES

1 k

Line/MH Number:	[11]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
Start Date:	UNK/UNK/2017
Ongoing:	YES

1.l

Line/MH Number:	[12]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DRUG ABUSE COCAINE]
Start Date:	UNK/UNK/2017
Ongoing:	NO End Date: UNK/UNK/2017

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FDA-CBER-2021-5683-0008478

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/18/2020
2.	Weight:	[212.0]
3.	Unit:	LB
4.	Height:	[67.7]
5.	Unit:	in
6.	Body Mass Index:	[32.5]

Vital Signs Details

7.a		
	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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FDA-CBER-2021-5683-0008479

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/18/2020
2.	Randomization Number:	[232097]
3.	Randomization Group:	[ ]

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FDA-CBER-2021-5683-0008480

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DWS]
5.b	Sample ID	[BP5DWT]
5.c	Sample ID	[BP5DWV]
5.d	Sample ID	[BPRHY0]
5.e	Sample ID	[BPRHY1]

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FDA-CBER-2021-5683-0008481

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DWG]

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FDA-CBER-2021-5683-0008482

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/18/2020 12:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008483

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

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FDA-CBER-2021-5683-0008484

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008485

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/10/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[98.8]
Unit:	F
Temperature Location:	ORAL CAVITY

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008486

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5F9X]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008487

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/10/2020 11:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008488

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008489

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR851D]
5.b	Sample ID	[BSH3ZY]
5.c	Sample ID	[BSH3ZZ]

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FDA-CBER-2021-5683-0008490

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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FDA-CBER-2021-5683-0008491

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms		
4.	Symptoms:	
	Was symptom present?	

Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

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FDA-CBER-2021-5683-0008492

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008493

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008494

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** HEALTH CARE UTILIZATION
Form Version: 20-Feb-2021 02:19	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

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FDA-CBER-2021-5683-0008495

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

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FDA-CBER-2021-5683-0008496

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008497

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008498

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008499

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

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FDA-CBER-2021-5683-0008500

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008501

Header Text: c4591001	
Visit: Follow-Up - Unscheduled	**Form:** DISPOSITION - FOLLOW-UP
Form Version: 15-Sep-2020 21:53	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008502

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008503

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008504

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961044 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Elevated Liver Enzymes	Sep/21/2020 UNK:UNK	NO End Date Time: Oct/12/2020 UNK:UNK	Repeating Pages

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008505

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Elevated Liver Enzymes]
4.	Start Date Time:	Sep/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/12/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020388029]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008507

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008508

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008509

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008510

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

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FDA-CBER-2021-5683-0008511

Header Text: c4591001

Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008512

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008513

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008514

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

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FDA-CBER-2021-5683-0008515

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008516

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

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FDA-CBER-2021-5683-0008517

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008518

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008519

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008520

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

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FDA-CBER-2021-5683-0008521

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008522

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008523

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

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FDA-CBER-2021-5683-0008524

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Oct/6/2020
2.	Primary Reason for Unblinding:	SUBJECT SAFETY CONCERN

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FDA-CBER-2021-5683-0008525

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

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FDA-CBER-2021-5683-0008526

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

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FDA-CBER-2021-5683-0008527

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008528

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/19/2021

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FDA-CBER-2021-5683-0008529

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008530

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation/Death :	Feb/9/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008531

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BSH4J8]
5.b	Sample ID	[BSH4JC]
5.c	Sample ID	[BNZNKL]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008532

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNKH]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008533

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/9/2021 10:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008534

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008535

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNR1]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008536

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/3/2021 11:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008537

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008538

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008539

Header Text: c4591001

Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008540

Header Text: c4591001

Visit: V104_MONTH6	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008541

Header Text: c4591001

Visit: V105_MONTH18 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008542

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008543

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008544

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008545

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961044	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008546

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 13:17:46 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008547

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Aug-18-2020 17:49:27 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008548

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Feb-09-2021 09:45:05 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008549

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 13:17:46 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Mar-08-2021 12:59:43 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Feb-22-2021 14:36:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Gabriela Obeidat	N/A	Dec-01-2020 16:29:00 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008550

Header Text: c4591001

Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Van Tran	Approved	Oct-30-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008551

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 17:48:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-18-2020 17:48:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008552

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-18-2020 17:48:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/18/2020	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008553

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961044 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Oct-12-2020 19:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:22:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	data is there
Oct-07-2020 05:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020388029 Elevated liver enzymes(onset date:21Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-18-2020 17:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961044	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1961	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 17:49:02 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** MALE	Initial Entry

Confidential

FDA-CBER-2021-5683-0008554

Time (US & Canada)		(pfe.gobeidat)		

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-18-2020 17:49:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-18-2020 17:49:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** WHITE	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008555

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 17:49:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008556

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-18-2020 17:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 17:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 17:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008557

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-18-2020 17:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** DIABETES MELLITUS TYPE 2 **Start Date:** UNK/UNK/1990 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** DIABETES MELLITUS TYPE 2	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/1990	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008558

1.b

Date	Location	User	Value	Reason
Aug-18-2020 17:51:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** HYPERTENSION **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** HYPERTENSION	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:51:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.c

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FDA-CBER-2021-5683-0008559

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-18-2020 17:52:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** DIABETIC NEUROPATHY **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** DIABETIC NEUROPATHY	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008560

Aug-18-2020 17:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** INSOMIA **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** INSOMIA	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-18-2020 17:53:16	ACV0PFEINFP6000	auto calc	**Data Entry:**	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008561

(UTC-06:00) Central Time (US & Canada)		(autocalc)	**Line/MH Number:** 5 **Medical History Term:** DEPRESSION **Start Date:** UNK/UNK/2017 **Ongoing:** YES	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** DEPRESSION	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Aug-18-2020 17:53:49 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Nu** 6	Initial Entry

Confidential

FDA-CBER-2021-5683-0008562

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Time (US & Canada)			**mber:** **Medical History Term:** CORONATY ARTERY DISEASE **Start Date:** Jul/4/2017 **Ongoing:** YES	

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** CORONATY ARTERY DISEASE	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jul/4/2017	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:53:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-18-2020 17:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008563

			Medical History Term: CONGESTIVE HEART FAILURE **Start Date:** Jul/4/2017 **Ongoing:** YES	

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** CONGESTIVE HEART FAILURE	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jul/4/2017	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-18-2020 17:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** CHRONIC KIDNEY DISEASE	Initial Entry

Confidential

FDA-CBER-2021-5683-0008564

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Start Date: UNK/UNK/2017 **Ongoing:** YES	

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** CHRONIC KIDNEY DISEASE	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-18-2020 17:54:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** SLEEP APNEA **Start Date:** UNK/UNK/2017	Initial Entry

Confidential
FDA-CBER-2021-5683-0008565
090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Ongoing: YES	

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** SLEEP APNEA	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:54:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-18-2020 17:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 10 **Medical History Term:** ANXIETY **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

Confidential

FDA-CBER-2021-5683-0008566

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ANXIETY	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008567

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.k

Date	Location	User	Value	Reason
Aug-18-2020 17:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** HYPERLIPIDEMIA **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** HYPERLIPIDEMIA	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008568

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.l

Date	Location	User	Value	Reason
Aug-18-2020 17:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 12 **Medical History Term:** DRUG ABUSE COCAINE **Start Date:** UNK/UNK/2017 **Ongoing:** NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008569

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.l Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 12	Initial Entry

1.l Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** DRUG ABUSE COCAINE	Initial Entry

1.l Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.l Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 17:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008570

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 212.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 67.7	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008571

Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 32.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-18-2020 17:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier ::** 1 **Temperature:** 98.4 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier ::** 1 **Temperature:** 98.4 **Temperature Unit:** **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008572

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Aug-18-2020 17:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008573

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-18-2020 17:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-18-2020 17:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 232097	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008574

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 17:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 17:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 20:01:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 17:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 17:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 20:01:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DWS	Initial Entry

Confidential

FDA-CBER-2021-5683-0008575

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 20:01:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DWS	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-18-2020 20:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DWT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 20:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DWT	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-18-2020 20:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DWV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 20:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DWV	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-18-2020 20:01:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHY0	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008576

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 20:01:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHY0	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-18-2020 20:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHY1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 20:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHY1	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008577

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 17:58:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 17:58:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 20:02:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 17:58:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 17:58:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 20:02:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DWG	Initial Entry

Confidential

FDA-CBER-2021-5683-0008578

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 20:02:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DWG	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008579

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020 12:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008580

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-18-2020 17:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008581

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-18-2020 17:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008582

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 18:34:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/10/2020	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008583

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-11-2020 10:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 98.8 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 98.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** F	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008584

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008585

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 18:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 18:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 18:35:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 18:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 18:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 18:35:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5F9X	Initial Entry

Confidential

FDA-CBER-2021-5683-0008586

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 18:35:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5F9X	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008587

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/10/2020 11:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008588

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-11-2020 10:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008589

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 17:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/8/2020	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008590

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 17:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 17:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 17:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 17:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 17:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 17:43:00 (UTC-06:00) Central	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0008591

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)		(pfe.lmartinez1)	**Sample ID:** BR851D	

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 17:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR851D	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 17:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 17:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZY	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 17:43:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 17:43:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZZ	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008592

Header Text: c4591001

Visit: End of Treatment - Unscheduled
Form: DISPOSITION - TREATMENT - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:55
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961044
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-12-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008593

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008594

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-25-2020 22:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-25-2020 16:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 2: Answered	SAE Report page 11 con med question if taking any con meds none or unknown was marked incorrectly, unknown instead of none, error was corrected and re faxed today. 25 NOV 2020.
Nov-25-2020 01:15:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - Please submit a SAE (#2020388029) safety followup with all con meds the subject was receiving at the onset of the SAE

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				elevated liver function tests
Oct-26-2020 17:55:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for SAE update on LFT elevation etiology if Med Records received
Oct-22-2020 19:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	medical records still pending for test result abnormality
Oct-21-2020 11:03:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Please followup with subject and physicians on a diagnosis for this lab test abnormality. If safety update is required, please submit a follow-up SAE form.
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Elevated Liver Enzymes	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 15:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 12:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 2: Closed	Response satisfies query
Dec-01-2020 16:29:57 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information

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Time (US & Canada)				
Dec-01-2020 16:29:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO End Date Time: Oct/12/2020 UNK:UNK	New Information
Nov-30-2020 14:11:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 2: Opened	GPD Clin: Please confirm that the event has or has not resolved to date - currently ongoing for more than 2 months. Thank you
Oct-13-2020 05:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Closed	closed per site response
Oct-12-2020 15:21:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	ae still ongoing
Oct-09-2020 15:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Opened	GPD Clin: Please confirm that the event has or has not resolved to date (currently ongoing for approximately 19 days). Thank you
Oct-07-2020 15:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

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If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-13-2020 12:19:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 7: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-12-2020 16:13:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 7: Answered	Changed data per query
Nov-11-2020 15:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 7: Opened	CLINICAL - No SAE update has been received for COVID test in HOSP (NO test performed); this is a request from the independent Data Monitoring Committee. Please submit.
Nov-04-2020 09:22:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Closed	Query closed; will follow for SAE update with the requested COVID test info
Oct-30-2020 18:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Reissued:Opened	Clinical - thank you; please submit that information (no COVID test in Hospital) as a SAE safety update
Oct-29-2020 18:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 6: Answered	Per subject COVID-19 testing was not completed

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Oct-29-2020 00:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Reissued:Opened	Clinical - Thank you; please submit this information as a SAE safety update (Awaiting Med Records to learn if COVID test performed)
Oct-28-2020 13:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 6: Answered	not known at this time, pending medical records
Oct-27-2020 21:39:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 6: Opened	Clinical – While awaiting additional records, please submit Awaiting Med Records to Determine if COVID testing was Performed as a SAE safety followup.
Oct-26-2020 17:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Query closed; will follow for SAE update on requested COVID test info, if med records received
Oct-22-2020 19:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 5: Answered	medical records still pending
Oct-21-2020 11:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020388029] to provide whether COVID testing was performed (yes/no) and if yes, the results.

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Oct-12-2020 12:05:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Oct-09-2020 15:56:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	requested dispo CRF completed
Oct-08-2020 09:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	CLINICAL SAE report states study treatment was unblinded at request of hospital physicians; please complete DISP CRF for treatment unblinding
Oct-08-2020 09:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Reason for SAE is 'Hospitalization'; however the original SAE form reason is 'Medically Significant'. Event may have more than 1 reason to be a SAE. Please submit a SAE safety f/u with additional SAE reason of 'hospitalization'
Oct-08-2020 05:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-07-2020 15:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-07-2020 15:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect?	Transcription Error

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			NO Did this serious event result in death? NO Did this serious event requi re or prolong hospitalizatio n? YES Did this serious event result in persistent or significant d isability/incapacity? NO Is this serious event life thr eatening? NO Other medically important s erious event NO	
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Elevated Liver Enzymes: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion

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				is expected to be YES for serious events. Please review and update as appropriate.
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason

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Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER *If Other, specify:* UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason

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Dec-03-2020 23:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Dec-02-2020 10:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	will be completed
Dec-02-2020 05:33:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020388029,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Not Recovered/Not Resolved in Safety database.Please confirm correct outcome.If safety update is required,please submit a follow-up form
Dec-01-2020 16:29:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RECOVERED/RESOLVED	New Information

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008604

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-07-2020 15:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-09-2020 15:57:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-08-2020 13:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-08-2020 13:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	**Data Entry:** 2020388029	Transcription Error
Oct-08-2020 09:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - number is the Subject ID number, not the SAE # [2020388029]
Oct-08-2020 05:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 10961044	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008605

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 09:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/11/2021	Initial Entry

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090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-09-2021 03:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Closed	Response satisfies query
Mar-08-2021 12:59:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	Original value is correct
Mar-08-2021 09:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Reissued: Opened	The Primary Reason for Unblinding in the Treatment Unblinded CRF is not ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION. Please review and update as appropriate.
Mar-05-2021 15:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	data is correct for this subject
Mar-05-2021 03:43:55 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7607708;The participant is willing to return for Vaccination 3,

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(US & Canada)				but the Primary Reason for Unblinding in the Treatment Unblinded CRF is not ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION. Please review and update as appropriate.
Feb-09-2021 09:43:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry :** Participant is willing to return for Vaccination 3 Participant is: eligible per local/ national recommendations a	Initial Entry

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090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Oct-09-2020 12:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/6/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Oct-09-2020 12:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** SUBJECT SAFETY CONCERN	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008610

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 09:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/9/2021	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008611

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-09-2021 16:33:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe francm73)	Query 1: Closed	Response satisfies query
Feb-09-2021 09:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	data correct visit was delayed on 19 jan 2021
Feb-09-2021 09:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Feb-09-2021 09:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/19/2021	Transcription Error
Feb-09-2021 09:44:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** OBTAINED Date Written Consent Obtained Feb/9/2021	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008612

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-10-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Feb-10-2021 11:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 11:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Feb/9/2021	Transcription Error
Feb-10-2021 11:38:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Consent Date was (19-Jan-21). Therefore, please determine if this Date should be updated. Otherwise, please clarify.
Feb-09-2021 09:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-09-2021 09:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-09-2021 09:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008613

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 09:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 09:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 10:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 14:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 09:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 09:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Feb/9/2021	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008614

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Feb-10-2021 10:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH4J8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 10:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH4J8	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-10-2021 11:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH4JC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH4JC	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-10-2021 11:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNKL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZNKL	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008615

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 09:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 09:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 10:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 14:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 09:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 09:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Feb/9/2021	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008616

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Feb-10-2021 10:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNKH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 10:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZNKH	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008617

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-15-2021 11:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Feb-12-2021 15:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-12-2021 15:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Changed Information
Feb-11-2021 15:29:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Reissued:Opened	CLINREQUERY: Reason for Delay does not meet the Protocol Criteria for Reasons for Delay of Vaccinations. There is no requirement that the Vaccine has to be done within a certain timeframe from the Revax Conf. Therefore, this question should be NO.
Feb-11-2021 10:10:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	no subject didn't have vaccination but there was a delay on 1-19-21 because the IRT system needed to be updated due to subject getting emergency unblinded and so subject was rescheduled. Please clarify on how this

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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				needs to be changed.
Feb-10-2021 13:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Did the Pt receive a Non-Study Vaccination? If Yes, please enter on the Non-Study Vaccination CRF. Otherwise, please clarify.
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of First Delay: Jan/19/2021 Reason(s) for Temporary De lay of Vaccination ANTICIPATED NON-ST UDY VACCINATION	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/9/2021 10:15	Initial Entry

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FDA-CBER-2021-5683-0008619

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008620

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-09-2021 10:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008621

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 20:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Mar-09-2021 10:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	entered
Mar-09-2021 04:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddyr51)	Query 1: Opened	DM: Kindly review and complete 'Nasal Swab' form at this visit. Thank you.
Mar-08-2021 12:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/3/2021	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008622

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 10:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 10:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 10:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 10:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 10:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 10:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNR1	Initial Entry

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FDA-CBER-2021-5683-0008623

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961044

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 10:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZNR1	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008624

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/3/2021 11:11	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008625

Header Text: c4591001
Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961044 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-08-2021 13:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008626

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-12-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-18-2020 17:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-18-2020 17:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-12-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/8/2020	Initial Entry
Aug-18-2020 17:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/18/2020	Initial Entry
Aug-18-2020 17:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/18/2020	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008627

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961044 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 13:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae3092\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008628

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008629

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/18/2020	Comments

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008630

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961056]
2.	Birth Date:	(b) (6)/1938
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008631

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/18/2020
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008632

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008633

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/18/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008634

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALLERGY TO LEVOFLOX]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALLERGY TO AVELOX]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALLERGY TO TRAMADOL]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[POST MENOPAUSE]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES

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FDA-CBER-2021-5683-0008635

1 f

Line/MH Number:	[6]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
Start Date:	UNK/UNK/2010
Ongoing:	YES

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008636

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/18/2020
2.	Weight:	[184.4]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[30.7]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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FDA-CBER-2021-5683-0008637

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008638

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/18/2020
2.	Randomization Number:	[232685]
3.	Randomization Group:	[ ]

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FDA-CBER-2021-5683-0008639

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DXW]
5.b	Sample ID	[BP5DXF]
5.c	Sample ID	[BP5DXX]
5.d	Sample ID	[BPRHYG]
5.e	Sample ID	[BPRHYH]

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FDA-CBER-2021-5683-0008640

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DX8]

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FDA-CBER-2021-5683-0008641

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/18/2020 17:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008642

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008643

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008644

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/10/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[97.5]
Unit:	F
Temperature Location:	ORAL CAVITY

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008645

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008646

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5FB8]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008647

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/10/2020 10:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008648

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008649

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR851B]
5.b	Sample ID	[BSH3ZT]
5.c	Sample ID	[BSH3ZV]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008650

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008651

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms		
4.	Symptoms:	
	Was symptom present?	

Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008652

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008653

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008654

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit | **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008655

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008656

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008657

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008658

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008659

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008660

Header Text: c4591001	
Visit: End of Treatment - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 15-Sep-2020 21:55	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008661

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008662

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** DATE OF VISIT - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008663

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008664

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961056 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Occipital Lobe Stroke	Feb/22/2021 UNK:UNK	NO End Date Time: Feb/26/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Bilateral Peripheral Vision Loss	Feb/22/2021 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Fatigue	Feb/23/2021 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	Patent Foramen Ovale	Feb/23/2021 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	Headache	Feb/22/2021 UNK:UNK	NO End Date Time: Feb/24/2021 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Worsening of Hypertension	Feb/23/2021 UNK:UNK	NO End Date Time: Feb/26/2021 UNK:UNK	Repeating Pages

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FDA-CBER-2021-5683-0008665

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Occipital Lobe Stroke]
4.	Start Date Time:	Feb/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/26/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

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090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021229873]

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FDA-CBER-2021-5683-0008667

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bilateral Peripheral Vision Loss]
4.	Start Date Time:	Feb/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Occipital Lobe Stroke]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0008669

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Occipital lobe stroke]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0008671

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Patent Foramen Ovale]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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FDA-CBER-2021-5683-0008672

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008673

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Feb/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/24/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Occipital lobe stroke]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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FDA-CBER-2021-5683-0008674

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008675

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Hypertension]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/26/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008677

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961056 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008679

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza Vaccine	Oct/24/2020	Repeating Pages

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008680

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Oct/24/2020

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FDA-CBER-2021-5683-0008681

Header Text: c4591001
Visit: Logs
Form: CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008682

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008683

Header Text: c4591001
Visit: Logs **Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961056 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008684

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008685

Header Text: c4591001
Visit: Logs **Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961056 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008686

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008687

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008688

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008689

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Lab Urinalysis		
1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result		
6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008690

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008691

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008692

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008693

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/31/2020
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008694

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008695

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/5/2021
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008696

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/5/2021

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008697

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008698

Header Text: c4591001

Visit: V101_VAX3 **Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Jan/5/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008699

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Lab Urinalysis			
1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result			
6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008700

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR858X]
5.b	Sample ID	[BSH460]
5.c	Sample ID	[BSH461]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008701

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR858S]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008702

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/5/2021 11:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008703

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Dec/31/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008704

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008705

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Death Details		
1.	Date of Collection / Notification of Death:	//

Cause of Death		
2.	Cause of Death Status:	
	Cause of Death:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008706

Header Text: c4591001	
Visit: V102_VAX4	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008707

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Lab Urinalysis			
1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result			
6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008708

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85JB]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008709

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/26/2021 12:01
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008710

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/2/2021
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008711

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/2/2021
3.	Comments:	[ ]

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008712

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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Confidential

FDA-CBER-2021-5683-0008713

Header Text: c4591001

Visit: V104_MONTH6	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008714

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008715

Header Text: c4591001

Visit: V105_MONTH18 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008716

Header Text: c4591001	
Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Mar/2/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008717

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008718

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008719

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008720

Header Text: c4591001
Visit: COHORT_SELECTION
Form: MAIN INFORMED CONSENT - Comments
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Sep-01-2020 10:01:17 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	DATA ENTRY ERROR SUBJECT WAS CONSENTED 08/18/2020
Form	Aug-19-2020 09:05:03 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	DATA ENTRY ERROR SUBJECT WAS CONSENTED 08/18/2020 Unknown
Form	Aug-19-2020 09:04:58 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	DATA ENTRY ERROR SUBJECT WAS CONSENTED 08/18/2020
Form	Aug-18-2020 21:18:57 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008721

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Sep-01-2020 10:01:17 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	DATA ENTRY ERROR SUBJECT WAS CONSENTED 08/18/2020
1	Aug-19-2020 09:05:03 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	DATA ENTRY ERROR SUBJECT WAS CONSENTED 08/18/2020 Unknown
1	Aug-18-2020 21:18:57 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008722

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Aug-18-2020 21:20:01 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008723

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008724

Header Text: c4591001	
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Form Version: 30-Jul-2020 21:27	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008725

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008726

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008727

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008728

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008729

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008730

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008731

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008732

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008733

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008734

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008735

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008736

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008737

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008738

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008739

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008740

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008741

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-05-2021 15:32:36 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008742

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008743

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008744

Header Text: c4591001

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Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008745

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008746

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008747

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008748

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008749

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008750

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008751

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008752

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008753

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008754

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008755

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008756

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008757

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008758

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008759

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008760

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Rocio Gutierrez	N/A	Mar-11-2021 12:04:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Van Tran	Approved	Mar-11-2021 07:34:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Yvette Davila	N/A	Mar-10-2021 16:48:41 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Van Tran	Approved	Mar-09-2021 13:37:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008761

Rocio Gutierrez	N/A	Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Feb-22-2021 14:44:26 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rocio Gutierrez	N/A	Jan-05-2021 15:16:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-05-2020 16:58:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rene Saenz	N/A	Nov-05-2020 15:43:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Oct-23-2020 18:26:44 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008762

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008763

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 21:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-18-2020 21:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008764

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_16
Sep-01-2020 10:01:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-01-2020 10:01:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/18/2020	Initial Entry
Sep-01-2020 10:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:**	Initial Entry
Sep-01-2020 06:36:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Reissued:Opened	DM 2: Thank you for response. Per response please consider to update the consent date as appropriate.

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008765

Aug-31-2020 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	Subject did consent on 08/18/2020
Aug-27-2020 00:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sakshi Sarmalkar LDM (pfe.sarmas06_ldm)	Query 1: Reissued:Opened	DM1: Thanks for the response. Please respond to this query once the Consent details are updated in Inform.
Aug-26-2020 09:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	ENTRY ERROR SUBJECT WAS CONSENTED
Aug-21-2020 06:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Reissued:Opened	DM: Thank you for response. Per response please consider to remove the item level comment and update the consent date as appropriate.
Aug-19-2020 13:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Reissued:Candidate	Reopening discrepancy due to primary column value change
Aug-19-2020 09:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	DATA ENTRY ERROR SUBJECT WAS CONSENTED 08/18/2020
Aug-19-2020 09:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Unknown	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008766

Header Text: c4591001
Visit: COHORT_SELECTION
Form: MAIN INFORMED CONSENT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Aug-19-2020 02:26:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4238005;Consent Obtained is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Aug-18-2020 21:18:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008767

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 21:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961056	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6) /1938	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 21:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-18-2020 21:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-18-2020 21:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** WHITE	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008768

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 21:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008769

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-18-2020 21:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 21:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 21:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008770

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Aug-18-2020 21:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** ALLERGY TO LEVOFLOX **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ALLERGY TO LEVOFLOX	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.b

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FDA-CBER-2021-5683-0008771

Date	Location	User	Value	Reason
Aug-18-2020 21:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** ALLERGY TO AVELOX **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ALLERGY TO AVELOX	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 21:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-18-2020 21:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3	Initial Entry

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FDA-CBER-2021-5683-0008772

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Medical History Term: ALLERGY TO TRAMADOL **Start Date:** UNK/UNK/2008 **Ongoing:** YES	

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ALLERGY TO TRAMADOL	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-18-2020 21:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** POST MENOPAUSE **Start Date:** UNK/UNK/1990	Initial Entry

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FDA-CBER-2021-5683-0008773

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Ongoing: YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** POST MENOPAUSE	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/1990	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 21:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-18-2020 21:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** OSTEOARTHRITIS **Start Date:** UNK/UNK/2012 **Ongoing:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008774

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 21:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-18-2020 21:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** OSTEOARTHRITIS	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UNK/UNK/2012	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 21:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-05-2020 15:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** Hypercholesterolemia **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008775

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.f Line/MH Number:

Date	Location	User	Value	Reason
Nov-05-2020 15:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-05-2020 15:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Hypercholesterolemia	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 15:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Nov-05-2020 15:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008776

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 184.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 65.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.7	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008777

7.a

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.3 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-18-2020 21:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008778

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** **Sponsor-Defined Ide** Not Applic	Initial Entry

Confidential

FDA-CBER-2021-5683-0008779

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)		(pfe.gobeidat)	**ntifier:** able **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-18-2020 21:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008780

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: RANDOMIZATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-18-2020 21:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-21-2020 05:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Closed	Response satisfies query
Aug-20-2020 17:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-20-2020 17:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 232685	Changed Information
Aug-20-2020 01:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	As per Impala, Randomization Number is 232685 . Please review and update as appropriate. "[newtod07 SDQ=798]"
Aug-18-2020 21:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 094053	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008781

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 21:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 21:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 21:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 21:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 21:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 21:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DXW	Initial Entry

5.a Sample ID

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FDA-CBER-2021-5683-0008782

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-18-2020 21:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DXW	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-18-2020 21:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DXF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 21:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DXF	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-18-2020 21:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DXX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 21:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DXX	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-18-2020 21:23:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHYG	Initial Entry

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008783

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 21:23:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHYG	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-18-2020 21:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHYH	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 21:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHYH	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008784

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 21:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 21:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 21:24:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 21:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 21:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 21:24:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DX8	Initial Entry

5.a Sample ID

Confidential

FDA-CBER-2021-5683-0008785

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-18-2020 21:24:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DX8	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008786

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Aug/18/2020 17:38	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008787

7. Route:

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-18-2020 21:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008788

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-18-2020 21:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008789

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 11:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/10/2020	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008790

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L
Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.5 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason

Confidential

FDA-CBER-2021-5683-0008791

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Sep-10-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008792

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** **Sponsor-Defined Ide** Not Applic	Initial Entry

Confidential

FDA-CBER-2021-5683-0008793

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)		(pfe.gobeidat)	**ntifier:** able **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 11:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008794

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 11:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 11:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 11:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 11:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5FB8	Initial Entry

5.a Sample ID

Confidential

FDA-CBER-2021-5683-0008795

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-10-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5FB8	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008796

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/10/2020 10:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008797

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-10-2020 11:29:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008798

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 12:36:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/8/2020	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008799

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 12:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 12:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 17:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 12:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 12:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 17:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR851B	Initial Entry

5.a Sample ID

Confidential

FDA-CBER-2021-5683-0008800

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-09-2020 17:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR851B	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 17:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 17:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZT	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 17:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 17:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZV	Initial Entry

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008801

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-09-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008802

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - Audit Trail
Form Version: 22-Apr-2020 21:02	**Form Status:**
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961056	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008803

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008804

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008805

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008806

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008807

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008808

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Occipital Lobe Stroke	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/22/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 08:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Deleted	SAE end date entered
Mar-08-2021 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Candidate	Clinical End date is 26Feb21; however, SAE report has no end date. Please update SAE report (#2021229873) with end date

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Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO End Date Time: Feb/26/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-09-2021 09:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddyr51)	Query 3: Opened	Clinical Serious criteria in both AE and SAE report include HOSP; however, AE CRF also includes Life-threatening. Severity grade is only 2 (not c/w life-threatening); please review and update serious criteria
Mar-08-2021 08:38:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Candidate	Clinical Serious criteria in both AE and SAE report include HOSP; however, AE CRF also includes Life-threatening. Severity grade is only 2 (not c/w life-threatening); please review and

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				update serious criteria
Mar-03-2021 05:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 13:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-02-2021 13:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	Transcription Error
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is

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				missing. Please review and update as appropriate.
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Occipital Lobe Stroke: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:** NO	Initial Entry

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Time (US & Canada)		(pfe.rgutierrez)		

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER *If Other, specify:* unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-02-2021 13:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-03-2021 05:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2021229873	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 08:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - SAE report (#2021229872) states 3rd study injection on 01JAN21; however VAX3 CRF states VAX3 was performed on 05Jan21. Please review, harmonize reporting, and update where applicable
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Bilateral Peripheral Vision Loss	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/22/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-02-2021 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatmen t(s), this event is due to: OTHER *If Other, specify:*	Transcription Error

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			Occipital Lobe Stroke	
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-02-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-04-2021 23:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Mar-04-2021 17:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	Per PI, this is not a Covid-19 symptom and is related to her stroke. Term will not be changed.
Mar-03-2021 15:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Since FATIGUE is one of the CDC-defined symptoms of COVID-19 (protocol section 8.1), please consider whether this symptom, could have been due to COVID-19 and should have triggered a potential COVID-19 illness visit
Mar-02-2021 13:23:59	ACV0PFEINFP6000	Rocio	**Data Entry:**	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe rgutierrez)	Fatigue	

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/23/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER *If Other, specify:* Occipital lobe stroke	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-04-2021 23:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe rosem19)	Query 1: Closed	Response satisfies query

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Mar-04-2021 17:55:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 17:55:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RECOVERED/ NOT RESOLVED	Transcription Error
Mar-03-2021 00:09:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7580193;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** RECOVERED/ RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-02-2021 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 07:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Mar-04-2021 17:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	confirmed
Mar-04-2021 10:46:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please confirm Patent Foramen Ovale was a new Diagnosis. Otherwise, provide clarification.
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Patent Foramen Ovale	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/23/2021 UNK:UNK	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER	Initial Entry

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			If Other, specify: unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-03-2021 18:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-06-2021 16:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Since HEADACHE is one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please consider whether this symptoms, could have been due to COVID-19 and should have triggered a potential COVID-19 Illness Visit
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/22/2021 UNK:UNK	Initial Entry

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008825

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO End Date Time: Feb/24/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 07:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008826

Mar-04-2021 18:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 18:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatmen t(s), this event is due to: OTHER *If Other, specify:* Occipital lobe stroke	Transcription Error
Mar-04-2021 10:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please clarify the Causality of RELATED to Study Treatment as Vaccine #4 was given on (26-Jan-21). Please confirm or update.
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008827

Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-03-2021 18:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008828

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Queries
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 09:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please clarify this AE Term of WORSENING of Hypertension. Was Hypertension a Pre-Existing Condition that should have been entered on the Medical History CRF, or was there a previous AE of Hypertension?
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Worsening of Hypertension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Feb/23/2021 UNK:UNK	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO End Date Time: Feb/26/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NOT RELATED If Not Related to study treatment (s), this event is due to:	Initial Entry

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			OTHER *If Other, specify:* unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-04-2021 18:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008831

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Jan-05-2021 15:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Form Created	

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008832

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-05-2021 15:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-05-2021 15:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-05-2021 15:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-05-2021 15:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-05-2021 15:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Oct/24/2020	Initial Entry

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008833

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 15:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Dec/31/2020	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008834

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-05-2021 15:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008835

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Jan/5/2021	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008836

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-05-2021 15:32:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/5/2021	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008837

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-05-2021 15:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Jan/5/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-05-2021 15:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-05-2021 15:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008838

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:** **Sponsor-Defined Id** Not Applic	Initial Entry

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FDA-CBER-2021-5683-0008839

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)		(pfe.rgutierrez)	**entifier:** able **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-05-2021 15:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008840

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Jan-06-2021 07:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-06-2021 07:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 07:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 07:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 07:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Jan/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 07:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR858X	Initial Entry

5.a Sample ID

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FDA-CBER-2021-5683-0008841

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Jan-06-2021 07:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR858X	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-06-2021 07:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSH460	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 07:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSH460	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-06-2021 07:04:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSH461	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 07:04:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSH461	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008842

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-06-2021 07:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-06-2021 07:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 07:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 07:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 07:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Jan/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 07:05:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR858S	Transcription Error
Jan-06-2021 07:04:59	ACV0PFEINFP6000	Gabriela	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0008843

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		Obeidat (pfe.gobeidat)	**Sample ID:** BR85S	

5.a Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 07:05:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-06-2021 07:05:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR858S	Transcription Error
Jan-06-2021 07:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Jan-06-2021 07:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR85S	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008844

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Jan/5/2021 11:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** LEFT	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008845

7. Route:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-05-2021 15:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008846

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-05-2021 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Dec/31/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-05-2021 15:16:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008847

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-26-2021 11:40:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/26/2021	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008848

Header Text: c4591001

Visit: V102_VAX4 | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** **Sponsor-Defined Ide** Not Applic	Initial Entry

Confidential

FDA-CBER-2021-5683-0008849

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)		(pfe.gobeidat)	**ntifier:** able **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 11:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008850

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 11:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 11:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-27-2021 08:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 11:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 11:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-27-2021 08:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR85JB	Initial Entry

5.a Sample ID

Confidential

FDA-CBER-2021-5683-0008851

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Jan-27-2021 08:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR85JB	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008852

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/26/2021 12:01	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

090177e196ae309f\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008853

7. Route:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-26-2021 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0008854

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 09:08:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Mar-11-2021 12:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	updated
Mar-11-2021 01:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Mar-10-2021 16:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/2/2021	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008855

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Contact Type:

Date	Location	User	Value	Reason
Mar-10-2021 16:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-10-2021 16:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Contact: Mar/2/2021	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008856

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961056

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-11-2021 12:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Mar/2/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-11-2021 12:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-11-2021 12:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0008857

Header Text: c4591001
Visit: Subject Status - Unscheduled
Form: SUBJECT STATUS - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961056
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-09-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-18-2020 21:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-18-2020 21:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-11-2021 01:09:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Deepthi Chandrasekaran (pfe.chandd38)	Query 2: Closed	Response satisfies query
Mar-10-2021 16:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 2: Answered	completed
Mar-09-2021 01:06:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajalakshmi Arumugam (pfe.arumur02)	Query 2: Opened	DM: V103 overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as Not Done with form level comment. If subject is no longer in the trial, complete the Disposition FUP form & Disposition-Treatment(EOT2)
Jan-25-2021 15:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Jan-25-2021 11:40:20	ACV0PFEINFP6000	Yvette Davila	Query 1: Answered	symptoms were due

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008858

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		to COVID vaccine given on 1-5-2021
Jan-21-2021 08:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (pfe.dubeys27)	Query 1: Opened	Illness ediary: As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 12JAN2021. But corresponding COVID Illness visit not reported. Please clarify.
Oct-09-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/8/2020	Initial Entry
Aug-18-2020 21:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/18/2020	Initial Entry
Aug-18-2020 21:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/18/2020	Initial Entry

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FDA-CBER-2021-5683-0008859

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961056 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 17:28:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae309f\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0008860

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection		
DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.		
1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

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FDA-CBER-2021-5683-0008861

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/19/2020

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FDA-CBER-2021-5683-0008862

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961062]
2.	Birth Date:	(b) (6) /1973
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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FDA-CBER-2021-5683-0008863

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/19/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008864

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

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FDA-CBER-2021-5683-0008865

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DISPOSITION - SCREENING
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/19/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

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FDA-CBER-2021-5683-0008866

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[C5-C7 FUSION]
	Start Date:	Feb/UNK/2020
	Ongoing:	NO End Date: Feb/UNK/2020
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HERNIATED C5-C7 DISC]
	Start Date:	Feb/UNK/2020
	Ongoing:	NO End Date: Feb/UNK/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[UMBILICAL HERNIA]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002

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FDA-CBER-2021-5683-0008867

1.d

Line/MH Number:	[4]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEPRESSION]
Start Date:	UNK/UNK/2002
Ongoing:	YES

1.e

Line/MH Number:	[5]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ANXIETY]
Start Date:	UNK/UNK/2015
Ongoing:	YES

1 f

Line/MH Number:	[6]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
Start Date:	UNK/UNK/2014
Ongoing:	YES

1.g

Line/MH Number:	[7]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
Start Date:	UNK/UNK/2014
Ongoing:	YES

1 h

Line/MH Number:	[8]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TESTOSTERONE DEFICIENCY]
Start Date:	UNK/UNK/2017
Ongoing:	YES

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FDA-CBER-2021-5683-0008868

1.i

Line/MH Number:	[9]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TONSILLECTOMY]
Start Date:	UNK/UNK/2002
Ongoing:	NO End Date: UNK/UNK/2002

1.j

Line/MH Number:	[10]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Intermittent lower back pain]
Start Date:	Aug/UNK/2019
Ongoing:	YES

1 k

Line/MH Number:	[11]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Car accident]
Start Date:	Aug/UNK/2019
Ongoing:	NO End Date: Aug/UNK/2019

1.l

Line/MH Number:	[12]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
Start Date:	UNK/UNK/2017
Ongoing:	YES

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FDA-CBER-2021-5683-0008869

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/19/2020
2.	Weight:	[220.4]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[29.9]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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FDA-CBER-2021-5683-0008870

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/19/2020
2.	Randomization Number:	[56745]
3.	Randomization Group:	[ ]

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FDA-CBER-2021-5683-0008871

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DZ9]
5.b	Sample ID	[BP5DZB]
5.c	Sample ID	[BP5DZC]
5.d	Sample ID	[BPRHZ8]
5.e	Sample ID	[BPRHZ9]

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FDA-CBER-2021-5683-0008872

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5DYM]

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FDA-CBER-2021-5683-0008873

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/19/2020 13:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008874

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

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FDA-CBER-2021-5683-0008875

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008876

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/9/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[97.8]
Unit:	F
Temperature Location:	ORAL CAVITY

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FDA-CBER-2021-5683-0008877

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5F99]

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FDA-CBER-2021-5683-0008878

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 13:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008879

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008880

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR850W]
5.b	Sample ID	[BSH3ZJ]
5.c	Sample ID	[BSH3ZK]

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FDA-CBER-2021-5683-0008881

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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FDA-CBER-2021-5683-0008882

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

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FDA-CBER-2021-5683-0008883

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008884

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008885

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit | **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

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FDA-CBER-2021-5683-0008886

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008887

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008888

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008889

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008890

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008891

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008892

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008893

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008894

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008895

Header Text: c4591001
Visit: Logs
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	bilateral lower extremity weakness	Oct/4/2020 09:00	NO End Date Time: Oct/5/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	worsening of hypertension	Sep/14/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	HYPOKALEMIA	Sep/UNK/2020 UNK:UNK	NO End Date Time: Sep/UNK/2020 UNK:UNK	Repeating Pages

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008896

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[bilateral lower extremity weakness]
4.	Start Date Time:	Oct/4/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/5/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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FDA-CBER-2021-5683-0008897

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020389670]

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening of hypertension]
4.	Start Date Time:	Sep/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [past medical history]

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10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0008900

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HYPOKALEMIA]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/UNK/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

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FDA-CBER-2021-5683-0008901

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [PERSONAL ILLNESS, possibly related to con med amlodipine]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020406150]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008902

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961062 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008903

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008904

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008905

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008906

Header Text: c4591001

Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008907

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008908

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008909

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008910

Header Text: c4591001

Visit: Logs | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008911

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008912

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008913

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008914

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008915

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008916

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008917

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008918

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008919

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008920

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Not Applicable //	Comments

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008921

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable //	Comments

Cause of Death

2.	Cause of Death Status:	Not Applicable
	Cause of Death:	Not Applicable [ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008922

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008923

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/14/2021

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008924

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008925

Header Text: c4591001

Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Jan/14/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008926

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85CN]
5.b	Sample ID	[BSH48L]
5.c	Sample ID	[BSH48M]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008927

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85CL]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008928

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/14/2021 10:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008929

Header Text: c4591001	
Visit: V102_VAX4	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008930

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNRC]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008931

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/3/2021 15:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0008932

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008933

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/4/2021
3.	Comments:	[ ]

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FDA-CBER-2021-5683-0008934

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0008935

Header Text: c4591001

Visit: V104_MONTH6	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008936

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008937

Header Text: c4591001

Visit: V105_MONTH18	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008938

Header Text: c4591001	
Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Mar/4/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008939

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008940

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961062	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008941

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 13:47:17 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

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FDA-CBER-2021-5683-0008942

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Aug-19-2020 20:59:08 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008943

Header Text: c4591001

Visit: Disposition - Unscheduled
Form: WITHDRAWAL OF CONSENT - Comments
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Jan-14-2021 10:34:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008944

Header Text: c4591001

Visit: Disposition | **Form:** WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Jan-14-2021 10:34:53 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008945

Header Text: c4591001

Visit: Disposition - Unscheduled
Form: DEATH DETAILS CODED - Comments
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Jan-14-2021 10:35:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008946

Header Text: c4591001

Visit: Disposition
Form: DEATH DETAILS CODED - Comments
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Jan-14-2021 10:35:10 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008947

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Jan-14-2021 10:36:03 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008948

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 13:47:17 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Mar-04-2021 13:03:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Feb-22-2021 14:45:58 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Nov-27-2020 12:17:08 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008949

Van Tran	Approved	Nov-09-2020 14:44:45 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Nov-09-2020 12:17:33 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-06-2020 17:31:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Nov-06-2020 14:19:55 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-05-2020 16:59:17 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008950

Header Text: c4591001

Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rene Saenz	N/A	Nov-05-2020 15:57:53 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Oct-30-2020 14:51:17 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008951

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-19-2020 20:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-19-2020 20:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008952

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-19-2020 20:57:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/19/2020	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008953

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Oct-21-2020 00:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-20-2020 13:57:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	AE CRF is entered please clarify query
Oct-20-2020 05:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020406150 hypokalemia(onset date:09Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-19-2020 20:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961062	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-22-2020 05:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	SDB data updated
Oct-21-2020 22:49:10 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	SAE Recon: to check latest SAE listing

Confidential

FDA-CBER-2021-5683-0008954

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Canada)				
Oct-21-2020 16:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	this has been updated- PLEASE UNLOCK THE MED HX PAGE and requery site to update
Oct-21-2020 04:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020406150 ,the date of birth was missing in Safety database but was recorded as (b) (6)/1973 in AE CRF. Please confirm date of birth. If safety update is required, please submit a follow-up form.
Aug-19-2020 20:57:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1973	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 20:57:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-19-2020 20:57:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008955

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Aug-19-2020 20:57:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** WHITE	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008956

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 20:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/19/2020	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008957

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-19-2020 20:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 20:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 20:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008958

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-19-2020 21:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** C5-C7 FUSION **Start Date:** Feb/UNK/2020 **Ongoing:** NO End Date: Feb/UNK/2020	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** C5-C7 FUSION	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Feb/UNK/2020	Initial Entry

1.a Ongoing:

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FDA-CBER-2021-5683-0008959

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-19-2020 21:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: Feb/UNK/2020	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-19-2020 21:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** HERNIATED C5-C7 DISC **Start Date:** Feb/UNK/2020 **Ongoing:** NO End Date: Feb/UNK/2020	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008960

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HERNIATED C5-C7 DISC	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Feb/UNK/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: Feb/UNK/2020	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-26-2020 09:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** UMBILICAL HERNIA **Start Date:** UNK/UNK/2002	New Information

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FDA-CBER-2021-5683-0008961

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Ongoing: NO End Date: UNK/UNK/2002	
Aug-19-2020 21:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** UMBILICAL CORD **Start Date:** UNK/UNK/2002 **Ongoing:** NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008962

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-26-2020 13:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Closed	Discrepancy has been closed.
Aug-26-2020 09:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Aug-26-2020 09:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** UMBILICAL HERNIA	New Information
Aug-22-2020 10:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Opened	Clarify UMBILICAL CORD as follows...Body site only reported. Specify the corresponding symptom, diagnosis or procedure being reported and update the verbatim term accordingly. Thank you.

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008963

Aug-22-2020 10:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Aug-22-2020 07:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Clarify UMBILICAL CORD as follows...Body site only reported. Specify the corresponding symptom, diagnosis or procedure being reported and update the verbatim term accordingly. Thank you.
Aug-22-2020 06:19:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-20-2020 10:59:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify UMBILICAL CORD as follows...Body site only reported. Specify the corresponding symptom, diagnosis or procedure being reported and update the verbatim term accordingly. Thank you.

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008964

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Aug-19-2020 21:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UMBILICAL CORD	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2002	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2002	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-19-2020 21:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** DEPRESSION **Start Date:** UNK/UNK/2002 **Ongoing:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008965

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** DEPRESSION	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2002	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-19-2020 21:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** ANXIETY **Start Date:** UNK/UNK/2015 **Ongoing:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008966

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ANXIETY	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2015	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Aug-19-2020 21:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** HYPERTENSION **Start Date:** UNK/UNK/2014 **Ongoing:** YES	Initial Entry

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FDA-CBER-2021-5683-0008967

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HYPERTENSION	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2014	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-19-2020 21:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** HYPERLIPIDEMIA **Start Date:** UNK/UNK/2014 **Ongoing:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008968

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HYPERLIPIDEMIA	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2014	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:07:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-19-2020 21:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** TESTOSTERONE DEFICIENCY **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008969

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** TESTOSTERONE DEFICIENCY	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-19-2020 21:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** TONSILLECTOMY **Start Date:** UNK/UNK/2002	Initial Entry

Confidential
FDA-CBER-2021-5683-0008970
090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Ongoing: NO End Date: UNK/UNK/2002	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008971

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-19-2020 21:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** TONSILLECTOMY	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2002	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 21:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2002	Initial Entry

1.j

Date	Location	User	Value	Reason
Nov-05-2020 15:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 10 **Medical History Term:** Intermittent lower back pain **Start Date:** Aug/UNK/2019	Initial Entry

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FDA-CBER-2021-5683-0008972

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Ongoing: YES	

1.j Line/MH Number:

Date	Location	User	Value	Reason
Nov-05-2020 15:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-05-2020 15:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Intermittent lower back pain	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 15:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Aug/UNK/2019	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Nov-05-2020 15:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Nov-06-2020 14:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** Car accident **Start Date:** Aug/UNK/2019	New Information

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FDA-CBER-2021-5683-0008973

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Ongoing: NO End Date: Aug/UNK/2019	
Nov-05-2020 15:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** Car accident **Start Date:** Aug/UNK/2019 **Ongoing:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008974

1.k Line/MH Number:

Date	Location	User	Value	Reason
Nov-05-2020 15:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-05-2020 15:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Car accident	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 15:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Aug/UNK/2019	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Nov-07-2020 10:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Nov-06-2020 14:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-06-2020 14:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: Aug/UNK/2019	New Information
Nov-06-2020 13:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Please clarify Ongoing for CAR ACCIDENT as this would only be

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008975

				expected to be a duration of one day. Please confirm and enter the END Date. Otherwise, please clarify.
Nov-05-2020 15:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

1.1

Date	Location	User	Value	Reason
Nov-05-2020 15:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 12 **Medical History Term:** Insomnia **Start Date:** UNK/UNK/2017 **Ongoing:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008976

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.l Line/MH Number:

Date	Location	User	Value	Reason
Nov-05-2020 15:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 12	Initial Entry

1.l Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-05-2020 15:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Insomnia	Initial Entry

1.l Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 15:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** UNK/UNK/2017	Initial Entry

1.l Ongoing:

Date	Location	User	Value	Reason
Nov-05-2020 15:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008977

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 220.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0008978

Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 29.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.9 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008979

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Aug-19-2020 21:02:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008980

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-19-2020 21:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 56745	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008981

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 21:17:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 21:17:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 21:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 21:17:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 21:17:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008982

Aug-19-2020 21:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DZ9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 21:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DZ9	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 21:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DZB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 21:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DZB	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 21:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DZC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 21:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DZC	Initial Entry

5.d

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008983

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-19-2020 21:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHZ8	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 21:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHZ8	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-19-2020 21:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRHZ9	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 21:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRHZ9	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008984

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 21:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 21:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 21:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 21:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 21:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008985

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Aug-19-2020 21:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5DYM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 21:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5DYM	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008986

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/19/2020 13:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008987

Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-19-2020 21:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008988

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-19-2020 21:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008989

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 10:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008990

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 10:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 10:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.8 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 10:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 10:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 10:45:38 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** F	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008991

Time (US & Canada)		(pfe.gobeidat)		

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 10:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008992

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 10:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 10:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 19:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 10:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 10:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008993

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Sep-10-2020 19:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5F99	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 19:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5F99	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008994

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/9/2020 13:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008995

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-10-2020 10:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0008996

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 19:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/7/2020	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008997

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-08-2020 15:22:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-08-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-08-2020 15:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection:	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008998

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

			Oct/7/2020	
Oct-08-2020 13:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Per Protocol, the Sample should have been taken. If done, please enter the data. Otherwise, please clarify.

5.a

Date	Location	User	Value	Reason
Oct-08-2020 15:22:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR850W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:22:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR850W	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 15:22:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:22:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZJ	Initial Entry

5.c

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0008999

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-08-2020 15:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSH3ZK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSH3ZK	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009000

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 20:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 20:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 20:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009001

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009002

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009003

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Form Created	

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009004

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-01-2020 05:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Closed	Response satisfies query
Nov-27-2020 12:17:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Nov-27-2020 12:17:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** bilateral lower extremity w eakness	New Information
Nov-26-2020 05:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Opened	SAE RECON 1: Form is unlock and unfrozen,please update term if final diagnosis is available. Also, please submit a follow up AEM form to also update term in Safety.

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009005

Nov-25-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 4: Answered	please unlock to change AE term
Nov-25-2020 04:32:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Opened	to reissue query as needed once medical records is available
Nov-23-2020 03:34:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Candidate	Pending final diagnosis
Nov-20-2020 09:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 4: Answered	Medical Records pending.
Nov-19-2020 08:10:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Opened	SAE RECON: AER#2020389670,the term was reported as ral Lower extremity paralysis in both database however per Clinical review, reports indicates reports no neurological findings. Please confirm final diagnosis and update accordingly.
Oct-21-2020 13:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Oct-20-2020 14:33:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 3: Answered	no other relevant information at this time.
Oct-20-2020 13:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	CLINICAL thank you for SAE report 'Hypokalemia' with 4 day hospitalization in

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				Sept. For SAE 'bilat Lower Ext paralysis' (#2020389670), please submit any relevant new information as a SAE safety followup report to that SAE #.
Oct-20-2020 08:28:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	SAE HAS BEEN ADDED
Oct-19-2020 20:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Please provide further information as a SAE safety update on the event of reversible bilat lower extremity paralysis x1 day including neurologic evaluation
Oct-14-2020 05:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	term updated in SDB
Oct-12-2020 20:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Reissued:Candidate	pending SDB update
Oct-12-2020 15:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	follow-up SAE submitted to correct verbiage of AE
Oct-11-2020 21:09:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-11-2020 08:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: AER#2020389670,the term was reported as 'Lower extremity paralysis' in Safety database while recorded as 'Bilateral

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				Lower extremity paralysis' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form.
Oct-09-2020 18:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-09-2020 18:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Bilateral Lower extremity paralysis	Transcription Error
Oct-08-2020 08:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL please clarify term to specify 1 side (left or right) or bilateral lower extremity paralysis
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Lower extremity paralysis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/4/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date Time: Oct/5/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

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Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-13-2020 12:22:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-12-2020 16:14:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 4: Answered	Changed data per query
Nov-11-2020 16:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	CLINICAL - no SAE update received with COVID test during Hosp information (NO Test Performed); this is a request from the independent DMC; please submit this followup for SAE #2020389670
Nov-07-2020 07:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 3: Closed	Response satisfies query
Nov-05-2020 18:00:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	site will submit follow-up in the AM with requested

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				data added
Nov-02-2020 23:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical - the trial Data Monitoring Committee has requested a report of COVID testing for all hospitalized subjects (done/NOT Done; result if done). Please submit a SAE safety update with the information (no test done)
Nov-02-2020 15:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 3: Answered	Per subject no COVID test done at hospital. Data entry is correct.
Oct-30-2020 18:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical - thank you; please submit this information (no COVID test in Hosp) as a SAE safety update
Oct-29-2020 18:12:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	per subject COVID-19 testing was not completed
Oct-28-2020 23:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical - Thank you; please submit that information to the SAE (Awaiting Med Records to learn if COVID test performed)
Oct-28-2020 14:24:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 3: Answered	no updates at this time and pending medical records
Oct-27-2020 21:40:21	ACV0PFEINFP6000	Kathryn Sewell	Query 3: Opened	Clinical – While

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(UTC-06:00) Central Time (US & Canada)		(pfe.sewelk02)		awaiting additional records, please submit Awaiting Med Records to Determine if COVID testing was Performed as a SAE safety followup.
Oct-26-2020 17:48:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for SAE update on COVID testing, if Med records received
Oct-22-2020 19:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 2: Answered	medical records still pending
Oct-21-2020 13:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020389670] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-08-2020 05:32:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Lower extremity paralysis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event

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				Number" is blank.
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-09-2020 16:31:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Nov-09-2020 12:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-09-2020 12:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* unknown	New Information

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FDA-CBER-2021-5683-0009013

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-08-2020 08:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (pfe finegansm)	Query 2: Reissued:Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [personal illness]. Please review and update as necessary
Nov-03-2020 12:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 2: Reissued:Candidate	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [personal illness]. - NOTE was made that MH records are still pending - set to candidate review
Nov-02-2020 15:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 2: Answered	medical records are still pending

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Nov-02-2020 05:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [personal illness]. Any symptoms, AEs or other key data should be collected on the adverse event page. Please review and update as necessary. "[survea03 SDQ=29146]"
Oct-26-2020 17:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-22-2020 09:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	Changed data per query
Oct-20-2020 17:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL please keep query open (no reply) until personal Illness update can be made

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Oct-20-2020 08:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	SITE IS PENDING RECORDS FOR FOLLOW UP
Oct-19-2020 20:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Please clarify what illness is being referred to by Personal Illness
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* per	Initial Entry

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			s o n a l i l l n e s s	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-07-2020 19:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-08-2020 05:32:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020389670	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009018

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961062
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** worsening of hypertension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/14/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 16:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	still ongoing

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Oct-12-2020 13:24:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please confirm if this AE is still Ongoing or not.
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** NOT RELATED	Initial Entry

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FDA-CBER-2021-5683-0009020
090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Time (US & Canada)		(pfe.ydavila)	If Not Related to study treatme nt(s), this event is due to: OTHER *If Other, specify:* past medical history	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RECOVERED/NOT RES OLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-08-2020 19:00:23	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	NO	

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FDA-CBER-2021-5683-0009022

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category:

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HYPOKALEMIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 05:09:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Per email confirmation from PSSR 'This is to confirm the onset date of hypokalemia is provided as UNK/SEP/2020 on AEM form and captured correctly as UNK/SEP/2020 in Safety database Argus. '
Oct-27-2020 01:09:01 (UTC-06:00) Central	ACV0PFEINFP6000	Ricell Ann Piojo	Query 2: Reissued:Candidate	SAE RECON: For PSSR review

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Time (US & Canada)		(pfe.quitor)		
Oct-26-2020 17:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	PER OUR REPORT THE START DATE IS LISTED AS UNK/SEP/2020 SO DATA IS ENTERED CORRECT AS IS. PLEASE TELL US WHERE 09/SEP/2020 IS LISTED?
Oct-26-2020 06:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: AER#2020406150
Oct-21-2020 13:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	no onset date yet in SAE report for hypokalemia (02Sep2020 is VAX 2 date)
Oct-21-2020 00:04:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020406150
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 09:03:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date Time: Sep/UNK/2020 UNK:UNK	Transcription Error
Oct-22-2020 09:00:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date Time:	Transcription Error

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			Sep/9/2020 UNK:UNK	
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date Time: Sep/UNK/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-26-2020 20:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Oct-26-2020 18:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 2: Answered	PER CRC THIS IS DOCUMENTED IN THE NARRATIVE ON SAE DOCUMENTATION SUBMITTED ON 22 OCT 2020
Oct-26-2020 17:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical – Thank you. If NO hospital Covid test performed is known, please submit this on a follow-up SAE form, as pertinent information

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				for this trial.
Oct-22-2020 09:04:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	subject did not get COVID tested
Oct-21-2020 13:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020406150] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-21-2020 00:03:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE HYPOKALEMIA: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitaliz	Initial Entry

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			ation? YES Did this serious event res ult in persistent or signific ant disability/incapacity? NO Is this serious event life th reatening? NO Other medically importan t serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-30-2020 19:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Oct-30-2020 10:24:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 2: Answer ed	Original value is correct

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Oct-30-2020 05:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [ILLNESS]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[naikp09 SDQ=25507]"
Oct-26-2020 17:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-22-2020 09:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event	New Information

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			is due to: OTHER *If Other, specify:* PERSONAL ILLNESS, possibly related to conmed amlodipine	

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Oct-22-2020 09:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	possibility per PI
Oct-21-2020 13:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL Please hold query open (no response) until medical update, on PI: "reasonable possibility that the event hypokalemia was related to the Con Med amlodipine" in SAE. Please review and update Other reason of 'Personal Illness', if appropriate.
Oct-20-2020 13:55:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	Pending medical records to confirm relation.
Oct-20-2020 12:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE safety reported "Investigator considered there was a reasonable possibility that the event hypokalemia

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				was related to the concomitant medication amlodipine". Please review and update Other reason of 'Personal Illness', if appropriate.
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* PERSONAL IL	Initial Entry

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			L N E S S	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-20-2020 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-21-2020 00:03:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020406150	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009033

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 10:35:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/8/2021	Initial Entry

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FDA-CBER-2021-5683-0009034

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-14-2021 10:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national re commendations and confirm ed to have received only pla cebo at Vaccination 1/2	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-14-2021 10:34:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/8/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-14-2021 10:34:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009036

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Jan-14-2021 10:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009037

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-14-2021 10:35:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009038

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 10:35:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/14/2021	Initial Entry

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FDA-CBER-2021-5683-0009039

Header Text: c4591001

Visit: V101_VAX3 **Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-14-2021 10:35:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/14/2021	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009040

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-14-2021 10:36:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/14/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-14-2021 10:36:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-14-2021 10:36:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009041

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Jan-14-2021 10:36:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-14-2021 10:36:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-14-2021 11:15:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021 10:36:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-14-2021 10:36:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Jan/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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Jan-14-2021 11:15:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR85CN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 11:15:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR85CN	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-14-2021 11:15:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSH48L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 11:15:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSH48L	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-14-2021 11:15:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSH48M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 11:15:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSH48M	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009043

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Jan-14-2021 10:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-14-2021 10:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-14-2021 11:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021 10:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-14-2021 10:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Jan/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009044

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Jan-14-2021 11:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR85CL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 11:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR85CL	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0009045

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/14/2021 10:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009046

Header Text: c4591001
Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961062 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-14-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009047

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 09:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/3/2021	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009048

Header Text: c4591001

Visit: V102_VAX4 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 09:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 09:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 09:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 09:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 09:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009049

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961062

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Feb-04-2021 09:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BNZNRC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BNZNRC	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009050

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/3/2021 15:07	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009051

Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-04-2021 15:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0009052

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 13:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/4/2021	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009053

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Contact Type:

Date	Location	User	Value	Reason
Mar-04-2021 13:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-04-2021 13:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Contact: Mar/4/2021	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009054

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-04-2021 13:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-04-2021 13:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-04-2021 13:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009055

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-07-2020 20:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-19-2020 21:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 20:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-07-2020 20:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/7/2020	Initial Entry
Aug-19-2020 21:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/19/2020	Initial Entry
Aug-19-2020 20:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/19/2020	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009056

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961062 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 13:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae3091\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0009057

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009058

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/29/2020

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009059

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961181]
2.	Birth Date:	(b) (6)/1957
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009060

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/29/2020
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009061

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009062

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation/Death	Aug/29/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009063

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIABETES MELLITUS TYPE 2]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERCHOLESTEROLEMIA]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SEASONAL ALLERGIES]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OBESITY]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009064

1.e

Line/MH Number:	[5]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS KNEES]
Start Date:	UNK/UNK/2005
Ongoing:	YES

1.f

Line/MH Number:	[6]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ENLARGED PROSTATE]
Start Date:	UNK/UNK/2018
Ongoing:	NO End Date: UNK/UNK/2019

1.g

Line/MH Number:	[7]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PROSTATECTOMY]
Start Date:	UNK/UNK/2019
Ongoing:	NO End Date: UNK/UNK/2019

1.h

Line/MH Number:	[8]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT KNEE REPLACEMENT]
Start Date:	UNK/UNK/2019
Ongoing:	NO End Date: UNK/UNK/2019

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009065

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.i

Line/MH Number:	[9]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIVERTICULITIS]
Start Date:	UNK/UNK/2005
Ongoing:	YES

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009066

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/29/2020
2.	Weight:	[265.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[35.9]

Vital Signs Details

7.a		
	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/29/2020
2.	Randomization Number:	[245869]
3.	Randomization Group:	[ ]

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FDA-CBER-2021-5683-0009068

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPRJ6L]
5.b	Sample ID	[BPRJ6M]
5.c	Sample ID	[BP96LR]
5.d	Sample ID	[BP96LS]
5.e	Sample ID	[BP96LT]

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FDA-CBER-2021-5683-0009069

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP9695]

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FDA-CBER-2021-5683-0009070

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/29/2020 12:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

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FDA-CBER-2021-5683-0009072

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/19/2020
2.	Erroneous Visit	

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Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/19/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[98.3]
Unit:	F
Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZP2B]

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FDA-CBER-2021-5683-0009075

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/19/2020 09:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0009076

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Date of Visit			
1.	Date of Visit	Oct/17/2020	Comments
2.	Erroneous Visit		

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Electronic Sample Tracking			
1.	Data Origin	SITE	
2.	Sample Type	SERUM	
3.	Sample Collected?	YES Date of Collection: Oct/17/2020	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]	Comments

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR9860]
5.b	Sample ID	[BSJ65D]
5.c	Sample ID	[BSJ65F]

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FDA-CBER-2021-5683-0009078

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

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FDA-CBER-2021-5683-0009079

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Signs and Symptoms		
1.	Date of Assessment:	Feb/22/2021
2.	Date of First Symptom Started:	Feb/18/2021
3.	Symptoms Ongoing?	YES

Symptoms		
4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

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090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

5.a	Symptoms - Other Text:	[lathargic]

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FDA-CBER-2021-5683-0009081

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Feb/21/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

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FDA-CBER-2021-5683-0009082

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Microbiology Specimen		
1.	Actual Date of Collection:	Feb/21/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[NALT unknown]

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FDA-CBER-2021-5683-0009083

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[CV54740]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[home swab collected]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Health Care Utilization		
1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** RESPIRATORY TREATMENT
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Respiratory Treatment			
1.	What is the treatment Identifier?	Not Done [ ]	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done	Comments
3.	Treatment:	Not Done	Comments
4.	Treatment:	Not Done [ ]	Comments
5.	Start Date:	Not Done //	Comments
6.	Ongoing?	Not Done	Comments

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FDA-CBER-2021-5683-0009088

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Illness Details		
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

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FDA-CBER-2021-5683-0009089

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category of Clinical Event :	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

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FDA-CBER-2021-5683-0009090

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Illness Details

1.	Category of Clinical Event:	Not Done	Comments
2.	Subcategory of Clinical Event:	Not Done	Comments
3.	Was a diagnosis obtained?	Not Done	Comments
4.	Toxicity Grade:	Not Done	Comments

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Form Version: 21-Aug-2020 02:49
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Done	Not Done	Not Done	Not Done		Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done

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FDA-CBER-2021-5683-0009092

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Lab Chemistry Details

1.	Lab Panel:	Not Done	Comments
2.	Laboratory Name and Address	Not Done [ ]	Comments
3.	Collection Date:	Not Done //	Comments
4.	Specimen Type:	Not Done	Comments

Lab Result

5.a

Sponsor ID:	Not Done [ ]	Comments
Test:	C Reactive Protein_PX329	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.b	Sponsor ID:	Not Done [ ]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Done [ ]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.d	Sponsor ID:	Not Done [ ]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.e	Sponsor ID:	Not Done [ ]	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.f	Sponsor ID:	Not Done [ ]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Done [ ]	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009096

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 21-Aug-2020 02:51
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Laboratory Data Hematology

1.	Lab Panel:	Not Done	Comments
2.	Laboratory Name and Address	Not Done [ ]	Comments
3.	Collection Date:	Not Done //	Comments
4.	Specimen Type:	Not Done	Comments

Lab Result

5.a

Sponsor ID:	Not Done [ ]	Comments
Test:	Hemoglobin_PX1	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009098

5.b	Sponsor ID:	Not Done [ ]	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Done [ ]	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009099

5.d	Sponsor ID:	Not Done [ ]	Comments
	Test:	Platelets_PX5	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.e	Sponsor ID:	Not Done [ ]	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.f	Sponsor ID:	Not Done [ ]	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Done [ ]	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009101

5.h	Sponsor ID:	Not Done [ ]	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.i	Sponsor ID:	Not Done [ ]	Comments
	Test:	Basophils_PX610	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009102

5.j

Sponsor ID:	Not Done [ ]	Comments
Test:	Lymphocytes_PX611	
Result:	Not Done [ ]	Comments
Not Done:	Not Done	Comments
LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009103

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - COVID
Form Version: 21-Aug-2020 02:50
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	**Record Identifier:**	**Systolic:**	**Diastolic:**	Repeating Pages
		Not Done	Not Done	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009104

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Form Comments
eCRF Audit Trail History

Vital Signs

1.	Date:	Not Done //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Done 1	
	Systolic:	Not Done [ ]	Comments
	Diastolic:	Not Done [ ]	Comments
	Respiratory Rate in respirations/minute:	Not Done [ ]	Comments
	Heart Rate in beats/minute:	Not Done [ ]	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009105

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Form Version: 21-Aug-2020 02:51
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details	Form Instance
1.	Not Done	Record Identifier: / Oxygen Saturation Not Done / Not Done	Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009106

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Vital Signs

1.	Date:	Not Done //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Done 1	
	SPO2 Pulse Oximetry %	Not Done [ ]	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009107

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009108

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Oxygenation Parameters

1.	Date Time of Assessment:	Not Done //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done [ ]	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done [ ]	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009109

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009110

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Concomitant Medications			
1.	What is the medication identifier?	Not Done [ ]	Comments
2.	Category:	Not Done	Comments
3.	Concomitant Medications Pre-specified:	Not Done	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Done [ ]	Comments
5.	Start Date:	Not Done //	Comments
6.	Ongoing?	Not Done	Comments

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009111

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Feb/21/2021	CHEST	X-RAY	NORMAL	Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009112

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
eCRF Audit Trail History
Form Audit Trail

Imaging		
1.	Date of Assessment:	Feb/21/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009113

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009114

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009115

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009116

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009117

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Oct/17/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009118

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009119

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit | **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009120

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009121

Adverse Event Report

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	

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14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009123

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009124

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009125

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Dec/1/2020	Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009126

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Dec/1/2020

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009127

Header Text: c4591001
Visit: Logs
Form: CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961181
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009129

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009130

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009131

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009132

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009133

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009134

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs		
1.	Date:	//

Vital Signs Details

2.		
	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009135

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009136

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009137

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009138

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009139

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009140

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009141

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/11/2021

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009142

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009143

Header Text: c4591001

Visit: V101_VAX3 **Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation/Death :	Jan/11/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009144

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85BH]
5.b	Sample ID	[BSH47N]
5.c	Sample ID	[BSH47P]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009145

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85BG]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009146

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 15:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009147

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/6/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009148

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009149

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009150

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/1/2021
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009151

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85M3]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009152

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/1/2021 16:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009153

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009154

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/1/2021
3.	Comments:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009155

Header Text: c4591001

Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009156

Header Text: c4591001

Visit: V104_MONTH6 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009157

Header Text: c4591001

Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009158

Header Text: c4591001

Visit: V105_MONTH18 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009159

Header Text: c4591001	
Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Mar/1/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009160

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/17/2020

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009161

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009162

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 18:50:51 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009163

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Aug-29-2020 22:13:24 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009164

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Sep-21-2020 18:37:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	error visit 3 has not occured yet

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009165

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Sep-21-2020 18:38:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	error visit 3 has not occured

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009166

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Oct-17-2020 16:01:49 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	PLEASE UNLOCK V3 VISIT DATE SO SITE CAN CONFIRM THE DATE, ALSO PLEASE UNOCK MED HIX PAGE FOR THIS SUBJECT

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009167

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
4	Oct-22-2020 21:05:44 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	
4	Sep-29-2020 18:49:54 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009168

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009169

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009170

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009171

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009172

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009173

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009174

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009175

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009176

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009177

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** ILLNESS DETAILS - SEVERE - Comments
Form Version: 17-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009178

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** ILLNESS DETAILS - SEVERE - Comments
Form Version: 17-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009179

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009180

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009181

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009182

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009183

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009184

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009185

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009186

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009187

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009188

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009189

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009190

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009191

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009192

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009193

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009194

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009195

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009196

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009197

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009198

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009199

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009200

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009201

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009202

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009203

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009204

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009205

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009206

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009207

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009208

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009209

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009210

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009211

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009212

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009213

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009214

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009215

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009216

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009217

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009218

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009219

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009220

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009221

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009222

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009223

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009224

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009225

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009226

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009227

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009228

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009229

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009230

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009231

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009232

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009233

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009234

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009235

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009236

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009237

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009238

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009239

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009240

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009241

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 f	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009242

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009243

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009244

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009245

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009246

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 h	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009247

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
5 h	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009248

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5 h	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009249

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
5 h	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009250

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009251

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009252

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009253

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009254

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009255

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009256

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009257

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009258

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009259

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009260

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009261

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.a	Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009262

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.a	Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009263

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.a	Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009264

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 21-Aug-2020 02:51 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009265

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009266

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.a	Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009267

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009268

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009269

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009270

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009271

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009272

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009273

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009274

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009275

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
4	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009276

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009277

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009278

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Jan-12-2021 09:33:13 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009279

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961181
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Van Tran	Approved	Mar-09-2021 18:50:51 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rocio Gutierrez	N/A	Feb-23-2021 16:15:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Feb-22-2021 17:49:31 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Rocio Gutierrez	N/A	Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009280

Van Tran	Approved	Feb-22-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Jan-12-2021 09:32:05 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Oct-29-2020 19:18:54 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009281

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-29-2020 22:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-29-2020 22:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009282

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-29-2020 22:11:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/29/2020	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009283

Header Text: c4591001
Visit: COHORT_SELECTION
Form: DEMOGRAPHY - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:55
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961181
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-29-2020 22:11:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961181	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6) /1957	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-29-2020 22:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-29-2020 22:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-29-2020 22:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** WHITE	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009284

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-29-2020 22:12:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/29/2020	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009285

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-29-2020 22:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-29-2020 22:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-29-2020 22:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009286

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-29-2020 22:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** DIABETES MELLITUS TYPE 2 **Start Date:** UNK/UNK/1990 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** DIABETES MELLITUS TYPE 2	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/1990	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.b

Confidential

FDA-CBER-2021-5683-0009287

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961181
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-29-2020 22:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** HYPERCHOLESTEROLEMIA **Start Date:** UNK/UNK/2016 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HYPERCHOLESTEROLEMIA	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2016	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-29-2020 22:15:40 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009288

Time (US & Canada)			**Line/MH Number:** 3 **Medical History Term:** SEASONAL ALLERGIES **Start Date:** UNK/UNK/2016 **Ongoing:** YES	

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** SEASONAL ALLERGIES	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2016	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-29-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4	Initial Entry

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FDA-CBER-2021-5683-0009289
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Medical History Term: OBESITY **Start Date:** UNK/UNK/2000 **Ongoing:** YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** OBESITY	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2000	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-29-2020 22:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** OSTEOARTHRITIS KNEES	Initial Entry

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090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Start Date: UNK/UNK/2005 **Ongoing:** YES	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** OSTEOARTHRITIS KNEES	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Aug-29-2020 22:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** ENLARGED PROSTATE **Start Date:** UNK/UNK/2018	Initial Entry

Confidential
FDA-CBER-2021-5683-0009291
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Ongoing: NO End Date: UNK/UNK/2019	

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ENLARGED PROSTATE	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2018	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2019	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-29-2020 22:18:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7	Initial Entry

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090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Medical History Term: PROSTATECTOMY **Start Date:** UNK/UNK/2019 **Ongoing:** NO End Date: UNK/UNK/2019	

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** PROSTATECTOMY	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2019	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:18:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2019	Initial Entry

1.h

Date	Location	User	Value	Reason

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009293

Aug-29-2020 22:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** RIGHT KNEE REPLACEMENT **Start Date:** UNK/UNK/2019 **Ongoing:** NO End Date: UNK/UNK/2019	Initial Entry

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** RIGHT KNEE REPLACEMENT	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2019	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2019	Initial Entry

1.i

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FDA-CBER-2021-5683-0009294

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961181
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-29-2020 22:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** DIVERTICULITIS **Start Date:** UNK/UNK/2005 **Ongoing:** YES	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** DIVERTICULITIS	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 22:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009295

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/29/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 265.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 35.9	Initial Entry

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FDA-CBER-2021-5683-0009296

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Time (US & Canada)				

7.a

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Record Identifier ::** 1 **Temperature:** 98.1 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009297

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-29-2020 22:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/29/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 245869	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009298

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-30-2020 23:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-30-2020 23:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-30-2020 23:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-30-2020 23:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-30-2020 23:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-30-2020 23:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRJ6L	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009299

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 23:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRJ6L	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-30-2020 23:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRJ6M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 23:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRJ6M	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-30-2020 23:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP96LR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 23:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP96LR	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-30-2020 23:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP96LS	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009300

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 23:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP96LS	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-30-2020 23:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP96LT	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 23:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP96LT	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009301

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-30-2020 23:31:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-30-2020 23:31:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-30-2020 23:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-30-2020 23:31:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-30-2020 23:31:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Aug/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-30-2020 23:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP9695	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009302

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 23:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP9695	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009303

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/29/2020 12:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** LEFT	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009304

Time (US & Canada)		(pfe.lmartinez1)		

7. Route:

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-29-2020 22:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009305

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-29-2020 22:21:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009306

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 16:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/19/2020	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009307

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier:** 1 **:** **Temperature:** 98.3 **Temperature Unit:** F **:** **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** F	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009308

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009309

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 16:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 16:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 18:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 16:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 16:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Sep/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 18:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZP2B	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009310

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 18:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZP2B	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009311

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/19/2020 09:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** LEFT	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009312

Time (US & Canada)		(pfe.gobeidat)		

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-21-2020 16:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009313

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961181 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 00:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 3: Closed	Closed as data updated.
Oct-20-2020 13:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-20-2020 13:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Oct/17/2020	Transcription Error
Oct-19-2020 02:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 3: Opened	DM: As per new comment entered, Kindly update data accordingly, Thank you.
Sep-23-2020 01:56:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 2: Closed	No issue. Data was entered in Error. Query not needed.
Sep-23-2020 01:55:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 1: Closed	Response satisfies query
Sep-23-2020 01:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Opened	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Sep-22-2020 14:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	Changed data per query
Sep-22-2020 14:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered.

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009314

				Please check whether other assessments are performed at this visit.
Sep-22-2020 05:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 1: Reissued:Opened	DM : If visit was entered by error, please tick the radio button to indicate that the visit entry is erroneous and update all forms in visit appropriately.
Sep-21-2020 18:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	attempted to clear page as visit has not occurred and entered in error. please delete page as I am not able to.
Sep-21-2020 18:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Visit, 19/Oct/2020 is a future date relative to when it was entered on 21/Sep /2020. Please correct.
Sep-21-2020 18:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/19/2020	New Information
Sep-21-2020 16:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/19/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-20-2020 13:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:**	Transcription Error
Sep-22-2020 14:16:52 (UTC-06:00) Central	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** ERRONEOUS VISIT	Initial Entry

Confidential
FDA-CBER-2021-5683-0009315
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001				
Visit: V3_MONTH1_POSTVAX2_L		**Form:** DATE OF VISIT - eCRF Audit Trail History		
Form Version: 22-Apr-2020 21:02		**Form Status:** Data Complete, Locked, Frozen, Verified		
Site No: 1096		**Site Name:** (1096) Ventavia Research Group		
Subject No: 10961181		**Subject Initials:** ---		
Generated By: pfe.levissc		**Generated Time (GMT):** 29-Mar-2021 10:39		
Time (US & Canada)				

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009316

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 16:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 16:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-17-2020 10:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Oct-17-2020 10:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-17-2020 10:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Oct/1	Transcription Error

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FDA-CBER-2021-5683-0009317

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			7/2 02 0	
Sep-30-2020 13:19:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 3: Closed	Response satisfies query
Sep-29-2020 18:50:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 3: Answered	Changed data per query
Sep-27-2020 04:21:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 3: Reissued: Opened	DM1: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY form is not unfrozen. Requesting to please consider adding form level 'Not applicable' comment, Thank you.
Sep-26-2020 12:24:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 3: Answered	site could not enter as not applicable as is it froze.
Sep-23-2020 04:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 3: Reissued: Opened	DM: This visit has been marked as Erroneous visit. Please confirm if any assessments were performed at this visit or it is entered in error. If entered in error; please consider adding form level 'Not applicable' comment on

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009318

				SAMP_TRK form. Thank you.
Sep-22-2020 20:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_03
Sep-22-2020 14:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 3: Answered	Changed data per query
Sep-22-2020 14:17:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Sep-22-2020 14:17:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-22-2020 14:17:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 14:17:27 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry :** NO	Transcription Error

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FDA-CBER-2021-5683-0009319
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Canada)				
Sep-22-2020 02:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 02:05:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW4769523;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Sep-21-2020 16:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 16:23:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry :** YES Date of Collection: Sep/19/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-23-2020 13:25:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-22-2020 21:06:35	ACV0PFEINFP6000	Yvette Davila	Query 1: Answered	data was cleared

Confidential

FDA-CBER-2021-5683-0009320

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		
Oct-22-2020 21:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:**	Initial Entry
Oct-20-2020 15:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: This field is only required to be entered if NO Sample was Taken. Please confirm and leave this field BLANK.
Sep-29-2020 18:49:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-17-2020 10:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR9860	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 10:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR9860	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-23-2020 16:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSJ65D	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009321

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.b Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 16:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSJ65D	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-23-2020 16:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BSJ65F	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 16:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BSJ65F	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009322

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 16:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-22-2021 15:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-22-2021 15:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-22-2021 15:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-22-2021 15:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** COVID_A	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009323

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/22/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/18/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009324

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** YES	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009325

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009326

			Symptom Present: NO	

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** NEW LOSS OF TASTE OR SMELL **Symptom Present:** NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

4.g

Confidential
FDA-CBER-2021-5683-0009327
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009328

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-22-2021 15:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 15:44:37	ACV0PFEINFP6000	Rocio	**Data Entry:**	Initial Entry

Confidential
FDA-CBER-2021-5683-0009329
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe rgutierrez)	**Symptoms - Other:** lathargic	

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-22-2021 15:44:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** lathargic	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009330

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54 **Form Status:**

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Form Created	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009331

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/21/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:** OTHER	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009332

Time (US & Canada)		(pfe rgutierrez)		

7. Test Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Mar-02-2021 07:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 2: Closed	Response satisfies query
Mar-01-2021 16:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-01-2021 16:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NALT unknown	Transcription Error
Feb-26-2021 10:08:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 2: Opened	CLINQUERY: Per CRF CCG section 8.31. if appropriate Trade Name is not available in the pre-defined list and unknown, please select 'OTHER' for Trade Name and enter 'NALT Unknown' in Trade Name Other.
Feb-26-2021 04:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Natasha Rajkumar (pfe.rajkun)	Query 1: Closed	Response satisfies query
Feb-25-2021 11:15:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009333

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Feb-25-2021 11:15:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** unknown	Transcription Error
Feb-25-2021 04:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Opened	DM: Manufacturer/test kit name provided does not uniquely match with the FDA List. Kindly update data as requested else please confirm and add text "CLIA-certified lab", Thank you.
Feb-22-2021 16:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** COVID/FLU Combo	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009334

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Feb-22-2021 16:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 16:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 17:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-23-2021 04:50:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-22-2021 16:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-22-2021 16:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES Date of Collection: Feb/22/2021	Initial Entry

5.a

Confidential

FDA-CBER-2021-5683-0009335

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Feb-24-2021 17:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sample ID:** CV54740	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 17:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** CV54740	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009336

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Feb-22-2021 16:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 16:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 16:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-22-2021 16:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** home swab collected	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009337

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:19 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:** NO	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009338

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

1.d

Date	Location	User	Value	Reason

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009339

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:19 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:** YES *Number of Visits or Contacts:* 1	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES *Number of Visits or Contacts:* 1	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:** NO	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009340

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:** NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Feb-22-2021 16:08:06	ACV0PFEINFP6000	Rocio	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0009341
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		Gutierrez (pfe rgutierrez)	NO	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009342

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009343

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Feb-22-2021 16:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009344

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-22-2021 16:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 2	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009345

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009346

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009347

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009348

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009349

5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009350

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009351

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009352

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009353

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009354

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009355

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009356

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009357

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009358

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009359

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009360

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009361

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009362

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009363

5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009364

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009365

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009366

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009367

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009368

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009369

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009370

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009371

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009372

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009373

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009374

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009375

5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0009376

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009377

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:** **Sponsor-Defined Iden** Not Do	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009378

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961181	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(pfe rgutierrez)	**tifier:**	ne	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009379

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.j Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Feb-22-2021 16:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009380

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Record Identifier::** Not Done **Systolic::** Not Done **Diastolic::** Not Done **Respiratory Rate in respirations/minute:** Not Done **Heart Rate in beats/minute:** Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009381

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Feb-22-2021 16:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009382

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Record Identifier::** Not Done **Oxygen Saturation:** Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Feb-22-2021 16:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009383

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Feb-22-2021 16:11:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009384

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009385

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 | **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

6. Ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009386

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53 **Form Status:**

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Feb-22-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Form Created	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009387

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/22/2021 **Form:** IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-22-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/21/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-22-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-22-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-22-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NORMAL	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009388

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-17-2020 10:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Oct/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-17-2020 10:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-17-2020 10:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009389

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Feb-25-2021 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009390

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-25-2021 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-25-2021 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-25-2021 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-25-2021 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-25-2021 11:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Dec/1/2020	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009391

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 09:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/6/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009392

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-12-2021 09:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009393

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 09:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/11/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009394

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Jan-12-2021 09:33:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/11/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009395

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-12-2021 09:33:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-12-2021 09:33:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-12-2021 09:33:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009396

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 13:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 13:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 08:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-19-2021 13:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-19-2021 13:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Jan/11/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009397

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Jan-13-2021 09:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Per Protocol, the Sample should have been collected. If collected, please update the CRF. Otherwise, please clarify.

5.a

Date	Location	User	Value	Reason
Jan-19-2021 13:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR85BH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BR85BH	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-19-2021 13:52:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH47N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:52:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH47N	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-19-2021 13:52:32 (UTC-06:00) Central	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** **Sample ID:** BSH47P	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009398

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(pfe.ydavila)		

5.c Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:52:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH47P	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009399

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 08:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-19-2021 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-19-2021 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Jan/11/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009400

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Jan-13-2021 09:53:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Per Protocol, the Swab should have been collected. If collected, please update the CRF. Otherwise, please clarify.

5.a

Date	Location	User	Value	Reason
Jan-19-2021 13:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR85BG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BR85BG	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009401

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/11/2021 15:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** LEFT	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009402

Time (US & Canada)		(pfe.ydavila)		

7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-12-2021 09:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009403

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-12-2021 09:32:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/6/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-12-2021 09:32:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009404

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 17:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/1/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009405

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-01-2021 16:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-01-2021 16:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 16:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 16:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Feb/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR85M3	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009406

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961181

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BR85M3	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009407

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/1/2021 16:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:** LEFT	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009408

Time (US & Canada)		(pfe rgutierrez)		

7. Route:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-24-2021 17:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** YES	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009409

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 16:10:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Mar/1/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009410

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Contact Type:

Date	Location	User	Value	Reason
Mar-01-2021 16:10:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-01-2021 16:10:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Contact: Mar/1/2021	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009411

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-03-2021 06:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ajit Malode (pfe maloda)	Query 3: Closed	Both dates are same.
Mar-02-2021 18:01:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 3: Answered	date of visit should be 103 per previous queries. data is correct as is. Please clarify query.
Mar-02-2021 06:33:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Opened	DMW7565608;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-01-2021 23:35:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Shubhada Ghisad (pfe.ghisas)	Query 2: Closed	V103 updated.
Mar-01-2021 16:11:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-01-2021 16:11:50 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry :** Mar/1/	Transcription Error

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FDA-CBER-2021-5683-0009412

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			2021	
Feb-25-2021 05:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Shubhada Ghisad (pfe.ghisas)	Query 2: Opened	DM: EOT2 is expected to entered once V103 is performed. So kindly consider to remove data from this page or else clarify. Thank you.
Feb-25-2021 02:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Adarsh Prabhu (pfe.prabha11)	Query 1: Closed	Incorrect query
Feb-24-2021 17:13:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	unable to remove or mark n/a completed in error.
Feb-24-2021 07:46:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7406753;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-23-2021 16:15:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Feb/1/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-23-2021 16:15:44	ACV0PFEINFP6000	auto calc	**Data Entry:**	Initial Entry

Confidential
FDA-CBER-2021-5683-0009413
090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		(autocalc)	OPEN LABEL TREATMENT	

3. Status:

Date	Location	User	Value	Reason
Mar-01-2021 16:11:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry
Feb-24-2021 17:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-24-2021 17:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-24-2021 17:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Transcription Error
Feb-24-2021 05:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: EOT2 (open label phase) is marked as COMPLETED but subject has not received vax 4 nor attended V103 (month follow up). Please review if page has been completed prematurely; else, update status to reflect reason for end of treatment
Feb-23-2021 16:15:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009414

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Subject Status

Date	Location	User	Value	Reason
Oct-17-2020 10:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-29-2020 22:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-29-2020 22:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-17-2020 10:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/17/2020	Initial Entry
Aug-29-2020 22:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/29/2020	Initial Entry
Aug-29-2020 22:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/29/2020	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009415

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961181 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-29-2020 18:35:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae3094\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009416

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009417

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/5/2020

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009418

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** DEMOGRAPHY
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961278]
2.	Birth Date:	(b) (6)/1974
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Confidential

FDA-CBER-2021-5683-0009419

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/5/2020
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009420

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009421

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DISPOSITION - SCREENING
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/5/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009422

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEART BURN]
	Start Date:	Aug/24/2020
	Ongoing:	NO End Date: Aug/24/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ALLERGY TO IODINE]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[KIDNEY STONES]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

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FDA-CBER-2021-5683-0009423

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LITHOTRIPSY]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[APPENDECTOMY]
	Start Date:	UNK/UNK/1987
	Ongoing:	NO End Date: UNK/UNK/1987
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[APPENDICITIS]
	Start Date:	UNK/UNK/1987
	Ongoing:	NO End Date: UNK/UNK/1987

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Confidential
FDA-CBER-2021-5683-0009424

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/5/2020
2.	Weight:	[169.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[28.1]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009425

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Sep/5/2020
2.	Randomization Number:	[82945]
3.	Randomization Group:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009426

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5F6G]
5.b	Sample ID	[BP5F6H]
5.c	Sample ID	[BP5F6J]
5.d	Sample ID	[BPRJFM]
5.e	Sample ID	[BPRJFN]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009427

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP5F5L]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009428

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/5/2020 18:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009429

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009430

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/25/2020
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009431

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/25/2020

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009432

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNFM]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009433

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/25/2020 12:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009434

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/27/2020
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009435

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR98W9]
5.b	Sample ID	[BSJ5PD]
5.c	Sample ID	[BSJ5PF]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009436

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/5/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009437

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Oct/5/2020
2.	Date of First Symptom Started:	Oct/3/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/6/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4 f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009438

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009439

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Microbiology Specimen

1.	Actual Date of Collection:	Not Done //	Comments
2.	Specimen Type:	Not Done	Comments
3.	Specimen Collection Location:	Not Done	Comments
4.	Assay Code and Description:	Not Done	Comments
5.	Device Type:	Not Done	Comments
6.	Trade Name:	Not Done	Comments
7.	Test Result:	Not Done	Comments
8.	Comments/Findings/Details:	Not Done [ ]	Comments
9.	Trade Name Other, Specify:	Not Done [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009440

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR8506]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009441

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Electronic Sample Tracking			
1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[self swab collected]	Comments

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009442

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	NO	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	NO	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	NO	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	NO	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	NO	Comments
1 f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	NO	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]	Comments

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009443

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** RESPIRATORY TREATMENT
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009444

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable [ ]	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable	Comments
3.	Treatment:	Not Applicable	Comments
4.	Treatment:	Not Applicable [ ]	Comments
5.	Start Date:	Not Applicable //	Comments
6.	Ongoing?	Not Applicable	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009445

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Illness Details			
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO	Comments
3.	Toxicity Grade:	2	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009446

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009447

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Illness Details			
1.	Category of Clinical Event:	Not Applicable	Comments
2.	Subcategory of Clinical Event:	Not Applicable	Comments
3.	Was a diagnosis obtained?	Not Applicable	Comments
4.	Toxicity Grade:	Not Applicable	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009448

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Form Version: 21-Aug-2020 02:49
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	See nested table	Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable
Not Applicable	Not Applicable	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009449

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Lab Chemistry Details

1.	Lab Panel:	Not Applicable	Comments
2.	Laboratory Name and Address	Not Applicable [ ]	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Specimen Type:	Not Applicable	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.b	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

5.c	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009451

5.d	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

5.e	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009452

5 f	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009453

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 21-Aug-2020 02:51
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009454

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Laboratory Data Hematology

1.	Lab Panel:	Not Applicable	Comments
2.	Laboratory Name and Address	Not Applicable [ ]	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Specimen Type:	Not Applicable	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.b	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009456

5.d	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

5.e	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5 f	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009458

5.h	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments
5.i	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009459

5.j	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable [ ]	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009460

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - COVID
Form Version: 21-Aug-2020 02:50
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	**Record Identifier:**	**Systolic:**	**Diastolic:**	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009461

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Form Comments
eCRF Audit Trail History

Vital Signs

1.	Date:	Not Applicable //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Applicable 1	
	Systolic:	Not Applicable [ ]	Comments
	Diastolic:	Not Applicable [ ]	Comments
	Respiratory Rate in respirations/minute:	Not Applicable [ ]	Comments
	Heart Rate in beats/minute:	Not Applicable [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009462

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Form Version: 21-Aug-2020 02:51
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details	Form Instance
1.	Not Applicable	Record Identifier: / Oxygen Saturation Not Applicable / Not Applicable	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009463

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Vital Signs			
1.	Date:	Not Applicable //	Comments

Vital Signs Details			
2.a	Record Identifier:	Not Applicable 1	
	SPO2 Pulse Oximetry %	Not Applicable [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009464

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009465

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Oxygenation Parameters			
1.	Date Time of Assessment:	Not Applicable //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable [ ]	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009466

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009467

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Concomitant Medications			
1.	What is the medication identifier?	Not Applicable [ ]	Comments
2.	Category:	Not Applicable	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable [ ]	Comments
5.	Start Date:	Not Applicable //	Comments
6.	Ongoing?	Not Applicable	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009468

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009469

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** IMAGING
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Imaging

1.	Date of Assessment:	Not Applicable //	Comments
2.	Location of Assessment:	Not Applicable	Comments
3.	Type of Imaging Exam:	Not Applicable	Comments
4.	Assessment:	Not Applicable	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009470

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/27/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_B

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009471

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Oct/27/2020	Comments
2.	Date of First Symptom Started:	Oct/26/2020	Comments
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/29/2020	Comments

Symptoms

4.a	Symptoms:	FEVER	
	Was symptom present?	NO	Comments
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	NO	Comments
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	NO	Comments
4.d	Symptoms:	CHILLS	
	Was symptom present?	NO	Comments
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	NO	Comments
4 f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	NO	Comments
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	YES	Comments
4.h	Symptoms:	DIARRHEA	
	Was symptom present?	NO	Comments
4.i	Symptoms:	VOMITING	
	Was symptom present?	NO	Comments

Symptoms - Other

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009472

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 10-Oct-2020 16:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

5.	Symptoms - Other Text:	[ ]

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FDA-CBER-2021-5683-0009473

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009474

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Microbiology Specimen

1.	Actual Date of Collection:	Not Done //	Comments
2.	Specimen Type:	Not Done	Comments
3.	Specimen Collection Location:	Not Done	Comments
4.	Assay Code and Description:	Not Done	Comments
5.	Device Type:	Not Done	Comments
6.	Trade Name:	Not Done	Comments
7.	Test Result:	Not Done	Comments
8.	Comments/Findings/Details:	Not Done [ ]	Comments
9.	Trade Name Other, Specify:	Not Done [ ]	Comments

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FDA-CBER-2021-5683-0009475

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Electronic Sample Tracking			
1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB_SELF	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[swab collected on site]	Comments

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009476

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR98WB]

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FDA-CBER-2021-5683-0009477

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	NO	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	NO	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	NO	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	NO	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	NO	Comments
1 f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	NO	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]	Comments

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	Comments

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FDA-CBER-2021-5683-0009478

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** RESPIRATORY TREATMENT
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

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FDA-CBER-2021-5683-0009479

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Respiratory Treatment

1.	What is the treatment Identifier?	Not Done [ ]	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done	Comments
3.	Treatment:	Not Done	Comments
4.	Treatment:	Not Done [ ]	Comments
5.	Start Date:	Not Done //	Comments
6.	Ongoing?	Not Done	Comments

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FDA-CBER-2021-5683-0009480

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Illness Details		
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

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FDA-CBER-2021-5683-0009481

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Illness Details

1.	Category of Clinical Event:	Not Done	Comments
2.	Subcategory of Clinical Event:	Not Done	Comments
3.	Was a diagnosis obtained?	Not Done	Comments
4.	Toxicity Grade:	Not Done	Comments

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FDA-CBER-2021-5683-0009483

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Form Version: 21-Aug-2020 02:49
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Done	Not Done	Not Done	Not Done		Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done

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FDA-CBER-2021-5683-0009484

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Lab Chemistry Details

1.	Lab Panel:	Not Done	Comments
2.	Laboratory Name and Address	Not Done [ ]	Comments
3.	Collection Date:	Not Done //	Comments
4.	Specimen Type:	Not Done	Comments

Lab Result

5.a	Sponsor ID:	Not Done [ ]	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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FDA-CBER-2021-5683-0009485

5.b	Sponsor ID:	Not Done [ ]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.c	Sponsor ID:	Not Done [ ]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.d	Sponsor ID:	Not Done [ ]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

5.e	Sponsor ID:	Not Done [ ]	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5 f	Sponsor ID:	Not Done [ ]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Done [ ]	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009488

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 21-Aug-2020 02:51
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	See nested table	Repeating Pages

Sponsor-Defined Identifier	Test:	Result:
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done
Not Done	Not Done	Not Done

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FDA-CBER-2021-5683-0009489

Laboratory Data Hematology

1.	Lab Panel:	Not Done	Comments
2.	Laboratory Name and Address	Not Done [ ]	Comments
3.	Collection Date:	Not Done //	Comments
4.	Specimen Type:	Not Done	Comments

Lab Result

5.a	Sponsor ID:	Not Done [ ]	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5.b	Sponsor ID:	Not Done [ ]	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

5.c	Sponsor ID:	Not Done [ ]	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

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5.d	Sponsor ID:	Not Done [ ]	Comments
	Test:	Platelets_PX5	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

5.e	Sponsor ID:	Not Done [ ]	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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5 f	Sponsor ID:	Not Done [ ]	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments
5.g	Sponsor ID:	Not Done [ ]	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009493

5.h	Sponsor ID:	Not Done [ ]	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

5.i	Sponsor ID:	Not Done [ ]	Comments
	Test:	Basophils_PX610	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009494

5.j	Sponsor ID:	Not Done [ ]	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Done [ ]	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [ ] High [ ] Unit	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009495

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** VITAL SIGNS - COVID
Form Version: 21-Aug-2020 02:50
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	**Record Identifier:**	**Systolic:**	**Diastolic:**	Repeating Pages
		Not Done	Not Done	Not Done	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009496

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Vital Signs

1.	Date:	Not Done //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Done 1	
	Systolic:	Not Done [ ]	Comments
	Diastolic:	Not Done [ ]	Comments
	Respiratory Rate in respirations/minute:	Not Done [ ]	Comments
	Heart Rate in beats/minute:	Not Done [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009497

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Form Version: 21-Aug-2020 02:51
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details	Form Instance
1.	Not Done	Record Identifier: / Oxygen Saturation Not Done / Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009498

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Vital Signs

1.	Date:	Not Done //	Comments

Vital Signs Details

2.a	Record Identifier:	Not Done 1	
	SPO2 Pulse Oximetry %	Not Done [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009499

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009500

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form
Form Comments
eCRF Audit Trail History

Oxygenation Parameters			
1.	Date Time of Assessment:	Not Done //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done [ ]	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done [ ]	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009501

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009502

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Concomitant Medications

1.	What is the medication identifier?	Not Done [ ]	Comments
2.	Category:	Not Done	Comments
3.	Concomitant Medications Pre-specified:	Not Done	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Done [ ]	Comments
5.	Start Date:	Not Done //	Comments
6.	Ongoing?	Not Done	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009503

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009504

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** IMAGING
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Imaging

1.	Date of Assessment:	Not Done //	Comments
2.	Location of Assessment:	Not Done	Comments
3.	Type of Imaging Exam:	Not Done	Comments
4.	Assessment:	Not Done	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009505

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/02/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Nov/2/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A1

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009506

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/02/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BSJ5SW]
5.b	Sample ID	[BSJ5SX]
5.c	Sample ID	[BR98YY]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009507

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Dec/01/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/1/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_B1

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009508

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Dec/01/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BSJ5ZJ]
5.b	Sample ID	[BSJ5ZK]
5.c	Sample ID	[BR8568]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009509

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0009510

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

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FDA-CBER-2021-5683-0009511

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/27/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

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FDA-CBER-2021-5683-0009512

Header Text: c4591001	
Visit: Follow-Up - Unscheduled	**Form:** DISPOSITION - FOLLOW-UP
Form Version: 15-Sep-2020 21:53	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

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FDA-CBER-2021-5683-0009513

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 - Unscheduled Visit on Oct/27/2020

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit			
1.	Date of Visit	Oct/27/2020	
2.	Erroneous Visit	ERRONEOUS VISIT	
COVID-19 Repeat Swab			
3.	COVID-19 Repeat Swab:	Not Applicable	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009514

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Electronic Sample Tracking			
1.	Data Origin	Not Applicable	Comments
2.	Sample Type	Not Applicable	Comments
3.	Sample Collected?	Not Applicable	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable [ ]	Comments

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	Not Applicable [ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009515

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Sialadenitis	Sep/13/2020 02:00	NO End Date Time: Sep/16/2020 09:00	Repeating Pages
2.	ADVERSE EVENT	2	Sore throat	Sep/13/2020 02:00	NO End Date Time: Sep/14/2020 17:00	Repeating Pages
3.	ADVERSE EVENT	3	Right swollen lymph node under jaw	Sep/13/2020 02:00	NO End Date Time: Sep/16/2020 09:00	Repeating Pages
4.	ADVERSE EVENT	4	Generalized muscle aches due to exercise	Sep/22/2020 19:00	YES	Repeating Pages
5. DELETED	ADVERSE EVENT	5	sore throat	Oct/3/2020 11:01	NO End Date Time: Oct/6/2020 UNK:UNK	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009516

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sialadenitis]
4.	Start Date Time:	Sep/13/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 09:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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FDA-CBER-2021-5683-0009517

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009518

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sore throat]
4.	Start Date Time:	Sep/13/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 17:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Personal infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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FDA-CBER-2021-5683-0009519

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009520

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right swollen lymph node under jaw]
4.	Start Date Time:	Sep/13/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 09:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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FDA-CBER-2021-5683-0009521

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Generalized muscle aches due to exercise]
4.	Start Date Time:	Sep/22/2020 19:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [due to exercise]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009524

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~5~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~sore throat~~]
4.	Start Date Time:	~~Oct/3/2020 11:01~~
5.	Is the adverse event still ongoing?	~~NO~~ ~~End Date Time:~~ ~~Oct/6/2020 UNK:UNK~~
6.	Toxicity Grade:	~~1~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~
9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~unknown~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~YES~~

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FDA-CBER-2021-5683-0009525

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Deleted, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~RECOVERED/RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0009526

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009527

Header Text: c4591001
Visit: Logs - Unscheduled
Form: MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Form Status: Not Started
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009528

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Oct/13/2020	Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009529

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Oct/13/2020

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009530

Header Text: c4591001

Visit: Logs | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009531

Header Text: c4591001
Visit: Logs - Unscheduled
Form: CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Form Status: Not Started
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009532

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009533

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009534

Header Text: c4591001

Visit: Logs | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009535

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009536

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009537

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009538

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009539

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009540

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009541

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009542

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009543

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009544

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Not Applicable //	Comments

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009545

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable //	Comments

Cause of Death

2.	Cause of Death Status:	Not Applicable
	Cause of Death:	Not Applicable [ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009546

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009547

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009548

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009549

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009550

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85D8]
5.b	Sample ID	[BSH498]
5.c	Sample ID	[BSH499]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009551

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR85DN]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009552

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 11:03
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009553

Header Text: c4591001	
Visit: V102_VAX4	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009554

Header Text: c4591001	
Visit: V102_VAX4	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZNKK]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009555

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/9/2021 10:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009556

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009557

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/11/2021
3.	Comments:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009558

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009559

Header Text: c4591001

Visit: V104_MONTH6 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009560

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009561

Header Text: c4591001

Visit: V105_MONTH18 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009562

Header Text: c4591001	
Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Mar/11/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009563

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/27/2020

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009564

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009565

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009566

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Sep-08-2020 22:16:39 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009567

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	Not Done
Form	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009568

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
1	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009569

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
2	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009570

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
3	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009571

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
4	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009572

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
5	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009573

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
6	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009574

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
7	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
7	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009575

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
8	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
8	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009576

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
9	Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	Not Done
9	Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009577

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
Form	Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009578

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
1	Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009579

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
2	Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009580

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
3	Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009581

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4	Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009582

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	
Form	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009583

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1.a	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
1.a	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009584

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1.b	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
1.b	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009585

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1.c	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
1.c	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009586

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1.d	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
1.d	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009587

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1.e	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
1.e	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009588

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1.f	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
1.f	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009589

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
2	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009590

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 15-Sep-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	
3	Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009591

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009592

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009593

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009594

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009595

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009596

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009597

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009598

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-15-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe rgutierrez)	unknown at this time
Form	Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	unknown at this time Unknown
Form	Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009599

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-15-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	unknown at this time
1	Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	unknown at this time --- Unknown
1	Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009600

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-15-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	unknown at this time
2	Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	unknown at this time Unknown
2	Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009601

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-15-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	Rocio Gutierrez (pfe.rgutierrez)	unknown at this time
3	Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	unknown at this time --- Unknown
3	Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009602

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009603

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009604

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** ILLNESS DETAILS - SEVERE - Comments
Form Version: 17-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009605

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009606

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** ILLNESS DETAILS - SEVERE - Comments
Form Version: 17-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009607

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009608

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009609

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009610

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009611

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009612

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009613

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009614

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009615

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009616

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009617

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009618

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009619

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009620

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009621

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009622

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009623

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009624

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009625

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009626

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009627

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009628

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009629

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009630

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009631

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009632

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009633

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009634

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009635

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009636

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009637

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009638

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009639

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009640

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009641

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009642

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009643

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009644

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009645

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009646

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009647

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009648

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009649

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009650

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009651

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009652

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009653

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009654

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009655

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009656

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009657

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009658

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009659

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009660

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009661

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009662

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009663

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009664

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009665

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009666

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009667

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009668

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009669

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009670

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009671

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009672

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009673

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009674

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009675

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009676

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009677

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009678

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009679

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009680

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009681

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009682

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009683

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009684

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009685

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009686

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009687

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009688

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009689

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009690

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009691

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009692

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009693

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009694

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009695

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009696

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009697

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009698

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009699

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009700

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009701

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009702

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009703

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009704

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009705

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009706

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009707

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009708

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020	**Form:** IMAGING - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009709

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009710

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: DATE OF VISIT - ILLNESS ONSET - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-30-2020 14:32:10 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009711

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
Form	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009712

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
1	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009713

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
2	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009714

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
3	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009715

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.a	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.a	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009716

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.b	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.b	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009717

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.c	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.c	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009718

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.d	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.d	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009719

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.e	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.e	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009720

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.f	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.f	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009721

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.g	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.g	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009722

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.h	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.h	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009723

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4.i	Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4.i	Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009724

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
Form	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
Form	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009725

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
1	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
1	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009726

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
2	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
2	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009727

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
3	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
3	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009728

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
4	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
4	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009729

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
5	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
5	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009730

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
6	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
6	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009731

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
7	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
7	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
7	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009732

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
8	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
8	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
8	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009733

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
9	Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Done
9	Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
9	Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009734

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
Form	Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009735

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
1	Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009736

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
2	Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009737

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
3	Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009738

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	
4	Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009739

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
Form	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009740

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1.a	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
1.a	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009741

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1.b	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
1.b	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009742

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1.c	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
1.c	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009743

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1.d	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
1.d	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009744

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1.e	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
1.e	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009745

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1.f	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
1.f	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009746

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
2	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009747

Header Text: c4591001

Visit: POT_COVID_ILL 2 **Form:** HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error
3	Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009748

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009749

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009750

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009751

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009752

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009753

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009754

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009755

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009756

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009757

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009758

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009759

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009760

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009761

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009762

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009763

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009764

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009765

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009766

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009767

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009768

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009769

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009770

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009771

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009772

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009773

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009774

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009775

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009776

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009777

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009778

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009779

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009780

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009781

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009782

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009783

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009784

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009785

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009786

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009787

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009788

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009789

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009790

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009791

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009792

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009793

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009794

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009795

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009796

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009797

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009798

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009799

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009800

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009801

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009802

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009803

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009804

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009805

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.b	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009806

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009807

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009808

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009809

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.c	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009810

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009811

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009812

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009813

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.d	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009814

Header Text: c4591001	
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Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009815

Header Text: c4591001	
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Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009816

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009817

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.e	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009818

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009819

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009820

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009821

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.f	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009822

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009823

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009824

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009825

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.g	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009826

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009827

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009828

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009829

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.h	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009830

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009831

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009832

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009833

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.i	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009834

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009835

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009836

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009837

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.j	Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009838

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009839

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009840

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009841

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009842

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009843

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2.a	Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009844

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009845

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009846

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2.a	Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009847

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009848

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009849

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009850

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009851

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009852

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009853

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009854

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009855

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009856

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009857

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009858

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009859

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009860

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
2	Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009861

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009862

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Done

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009863

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 | **Form:** DATE OF VISIT - REPEAT SWAB - Comments

Form Version: 10-Oct-2020 15:57 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Nov-11-2020 10:08:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009864

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009865

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - Comments

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009866

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - Comments

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009867

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - Comments

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
3	Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009868

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - Comments

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	Lizatte Martinez (pfe.lmartinez1)	visit entered in error Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009869

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-14-2021 13:27:28 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009870

Header Text: c4591001

Visit: Disposition | **Form:** WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Jan-14-2021 13:27:28 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009871

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-14-2021 13:27:38 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009872

Header Text: c4591001

Visit: Disposition | **Form:** DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Jan-14-2021 13:27:38 (UTC-06:00) Central Time (US & Canada)	Gabriela Obeidat (pfe.gobeidat)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009873

Header Text: c4591001

Visit: V101_VAX3 | **Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-19-2021 10:37:19 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009874

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Gabriela Obeidat	N/A	Mar-11-2021 18:13:41 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Van Tran	Approved	Feb-22-2021 16:53:21 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Yvette Davila	N/A	Dec-01-2020 14:35:05 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Van Tran	Approved	Nov-11-2020 11:32:01 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Lizatte Martinez	N/A	Nov-11-2020 10:08:43 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009875

Affidavit:
N/A

Van Tran	Approved	Nov-04-2020 13:18:08 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lizatte Martinez	N/A	Nov-04-2020 09:38:28 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-04-2020 09:29:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Nov-03-2020 09:38:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-02-2020 18:32:16 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009876

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-08-2020 22:15:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-08-2020 22:15:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009878

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Sep-08-2020 22:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** OBTAINED Date Written Consent Obtained Sep/5/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009879

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Sep-08-2020 22:15:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961278	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6) /1974	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-08-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-08-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-08-2020 22:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** WHITE	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009880

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 03:36:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Per PI confirmation-no COVID illness symptom
Oct-05-2020 11:42:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Query 1: Answered	Per PI not COVID illness symptom. AE was reported.
Oct-01-2020 10:41:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?? for the COVID-19 symptoms or diagnosis on 13SEP2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-08-2020 22:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/5/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009881

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-29-2020 15:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Closed	Response satisfies query
Oct-29-2020 12:00:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-29-2020 12:00:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/5/2020	Transcription Error
Oct-29-2020 01:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	All screening procedures done on 05Sep2020 and vaccination 1 administered on 05Sep2020. But date is entered as 08Sep2020 in this CRF. Please verify and update this date. Else clarify.
Sep-08-2020 22:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-08-2020 22:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-08-2020 22:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009882

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Sep-08-2020 22:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** HYPERTENSION **Start Date:** UNK/UNK/2018 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-04-2020 11:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 1: Closed	Response satisfies query
Nov-04-2020 09:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	PLEASE UNFREEZE CRF PAGE SO DATA CAN BE UPDATED
Nov-03-2020 19:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 1: Opened	Per source 27Oct20 subject reported forgetting to mention "history of seasonal allergies" on V1 as baseline. Please consider adding to medical history as this seems to suggest prior history.
Sep-08-2020 22:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HYPERTENSION	Initial Entry

1.a Start Date:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009883

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-08-2020 22:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-08-2020 22:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** HEART BURN **Start Date:** Aug/24/2020 **Ongoing:** NO End Date: Aug/24/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009884

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** HEART BURN	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Aug/24/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: Aug/24/2020	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-08-2020 22:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** ALLERGY TO IODINE **Start Date:** UNK/UNK/2005 **Ongoing:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009885

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ALLERGY TO IODINE	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-08-2020 22:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** KIDNEY STONES **Start Date:** UNK/UNK/2005 **Ongoing:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009886

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** KIDNEY STONES	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-08-2020 22:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** LITHOTRIPSY **Start Date:** UNK/UNK/2013 **Ongoing:** NO End Date: UNK/UNK/2013	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009887

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LITHOTRIPSY	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/2013	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/2013	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-08-2020 22:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** APPENDECTOMY **Start Date:** UNK/UNK/1987 **Ongoing:** NO End Date: UNK/UNK/1987	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009888

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** APPENDECTOMY	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/1987	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/1987	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-08-2020 22:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** APPENDICITIS **Start Date:** UNK/UNK/1987 **Ongoing:** NO End Date: UNK/UNK/1987	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009889

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** APPENDICITIS	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** UNK/UNK/1987	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 22:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO End Date: UNK/UNK/1987	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009890

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/5/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 169.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 65.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 28.1	Initial Entry

7.a

Confidential

FDA-CBER-2021-5683-0009891

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 98.0 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009892

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-08-2020 22:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/5/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-08-2020 22:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 82945	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009893

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-09-2020 08:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 08:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-09-2020 08:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 08:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 08:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 08:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5F6G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 08:07:01	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0009894

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BP5F6G	

5.b

Date	Location	User	Value	Reason
Sep-09-2020 08:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5F6H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 08:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5F6H	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-09-2020 08:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5F6J	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 08:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BP5F6J	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-09-2020 08:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRJFM	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 08:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRJFM	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009895

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.e

Date	Location	User	Value	Reason
Sep-09-2020 08:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BPRJFN	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 08:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BPRJFN	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009896

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-09-2020 08:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 08:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-09-2020 08:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 08:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 08:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 08:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BP5F5L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 08:06:10	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009897

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BP5F5L	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009898

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Sep/5/2020 18:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** LEFT	Initial Entry

7. Route:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009899

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-08-2020 22:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009900

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-08-2020 22:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009901

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-26-2020 14:25:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/25/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009902

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-28-2020 11:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-28-2020 11:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.5 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-28-2020 11:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-28-2020 11:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-28-2020 11:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-28-2020 11:57:48 (UTC-06:00) Central Time	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** ORAL CAVITY	Initial Entry

Confidential

FDA-CBER-2021-5683-0009903

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.gobeidat)		

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009904

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-26-2020 14:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-26-2020 14:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-26-2020 14:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-26-2020 14:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-26-2020 14:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-26-2020 14:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNFM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-26-2020 14:25:53	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009905

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BNZNFM	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009906

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/25/2020 12:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

7. Route:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009907

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-28-2020 11:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009908

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-27-2020 12:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/27/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009909

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 16:42:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 16:42:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-27-2020 16:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 16:42:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 16:42:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 16:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR98W9	Transcription Error
Oct-27-2020 16:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR98WB	Initial Entry

5.a Sample ID

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009910

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-27-2020 16:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR98W9	Transcription Error
Oct-27-2020 16:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BR98WB	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 16:58:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSJ5PD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 16:58:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSJ5PD	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 16:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BSJ5PF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 16:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** BSJ5PF	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009911

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 16:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-08-2020 16:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-08-2020 16:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-08-2020 16:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Oct/5/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-08-2020 16:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** COVID_A	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009912

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/5/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-08-2020 16:16:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/3/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-31-2020 08:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Praful Prabhakar (pfe.prabhp12)	Query 2: Closed	Response satisfies query
Oct-30-2020 15:25:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO Date of Last Symptom Resolved: Oct/6/2020	New Information
Oct-30-2020 14:38:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	Changed data per query
Oct-30-2020 09:21:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 2: Opened	DM2: Per CRF CRs if the symptoms from COVID A were not resolved, a new COVID visit should not be added. If symptoms on 27 Oct were ongoing please remove data from COVID B and mark erroneous. The swab from 27 Oct should be added as a reswab on reswab form.

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009913

Oct-29-2020 11:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Closed	Response satisfies query
Oct-28-2020 12:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	noted for future reference when dates are overlapping no COVID-B visit needed, but in this case it was completed therefore data correct as is and no updates at this time.
Oct-28-2020 10:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Divya M (pfe md09)	Query 1: Opened	DM: COVID_B visit is conducted while symptoms from 1st visit is ongoing. Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Oct-08-2020 16:16:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** FEVER	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009914

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** NO	Initial Entry

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FDA-CBER-2021-5683-0009915

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom P resent:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009916

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW LOSS OF TASTE OR SMELL **Symptom Present:** NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009917

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009918

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-08-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009919

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-16-2020 08:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Oct-15-2020 11:47:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	Query 1: Answered	updated
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-15-2020 02:49:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Opened	CLIQUERY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-13-2020 15:25:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Candidate	CLIQUERY: Per CCG's 'Not Done' needs to be applied to the CRF if local test was not completed. Please update.
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason

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FDA-CBER-2021-5683-0009920

Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009921

Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-15-2020 11:47:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** Not Done	Initial Entry
Oct-08-2020 16:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009922

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 16:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 16:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 17:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 16:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 16:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** YES Date of Collection: Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 17:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR8506	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:43:06	ACV0PFEINFP6000	Behnaz	Query 1: Closed	Response satisfies

Confidential

FDA-CBER-2021-5683-0009923

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)		Yousefzadeh-Khiabani (pfe.youseb01)		query
Oct-14-2020 08:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Reissued:Candidate	Confirming barcode with VRD
Oct-13-2020 16:36:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	subject self swabbed and barcode had 6 characters
Oct-13-2020 16:35:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Reissued:Opened	DM1: Self swab barcodes are 7 characters. Please confirm self swab was collected and correct as appropriate.
Oct-12-2020 20:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	barcode only has 6 characters
Oct-08-2020 17:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Oct-08-2020 17:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR8506	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009924

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry
Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry
Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 21:14:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_05
Oct-13-2020 15:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-13-2020 15:20:33	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If

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FDA-CBER-2021-5683-0009925

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(UTC-06:00) Central Time (US & Canada)				no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-13-2020 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-13-2020 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry :** NO	Initial Entry
Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry :**	Initial Entry
Oct-13-2020 14:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Reissued:Opened	DM Query: Per CRF Completion Requirements Section 8.32, the responses on this form should not be 'Not applicable.' If only the subject self swab was collected, the response to this item should be 'No' with the reason provided in Item 4.
Oct-12-2020 20:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	correct as is, subject collected a self swab
Oct-12-2020 02:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4929485;Sample Collected is not expected to be Unknown or Not Applicable. Please

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090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

				review and update appropriately or clarify
Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-13-2020 15:24:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-13-2020 15:24:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** self swab collected	Transcription Error
Oct-13-2020 15:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Oct-13-2020 15:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** self swab collected	Initial Entry
Oct-13-2020 15:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-08-2020 16:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009927

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** Not Applicable	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 07:10:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Closed	Response satisfies query
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0009928

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe rgutierrez)		
Oct-14-2020 14:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Opened	DM: Per CRF CRs Section 8.35.2, Yes or No must be selected for each question.
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009929

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009930

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009931

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-14-2020 19:05:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** NO	Transcription Error
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** YES *Number of Visits or Contacts:* 1	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0009932
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			**Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** Not Applicable	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-14-2020 19:05:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Transcription Error
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** YES *Number of Visits or Contacts:* 1	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:**	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009933

Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** **Type of Practitioner:** Not Applicable **Occurrence of Visits or Contacts:** Not Applicable	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Oct-14-2020 19:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:**	Initial Entry
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-14-2020 19:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-14-2020 19:00:01 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rocio Gutierrez	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0009934
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.rgutierrez)		
Oct-08-2020 16:18:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009935

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009936

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-15-2020 11:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry
Oct-15-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:**	Initial Entry
Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Unknown	Initial Entry
Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-15-2020 15:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_CEIDT008_01
Oct-15-2020 11:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-15-2020 11:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** NO	Initial Entry
Oct-15-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:**	Initial Entry
Oct-14-2020 07:12:43	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Reissued:Opened	DM1: The responses in this form should

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(UTC-06:00) Central Time (US & Canada)				not be 'Unknown' or 'Not Applicable'. This form is required and requires a response to each item.
Oct-13-2020 03:15:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Reissued:Candidate	Reopening discrepancy due to primary column value change
Oct-12-2020 20:26:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	Original value is correct
Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Unknown	Initial Entry
Oct-09-2020 05:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4929494;Was a diagnosis obtained for Potential COVID-19 Illness? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-15-2020 11:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:** 2	Initial Entry
Oct-15-2020 11:48:21 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rocio Gutierrez (pfe rgutierrez)	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0009938
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)				
Oct-12-2020 20:25:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Unknown	Initial Entry
Oct-08-2020 16:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009939

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009940

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009941

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential
FDA-CBER-2021-5683-0009942
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential

FDA-CBER-2021-5683-0009943

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009944

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009945

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential
FDA-CBER-2021-5683-0009946
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential

FDA-CBER-2021-5683-0009947

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009948

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009949

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009950

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009951

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential
FDA-CBER-2021-5683-0009952
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential

FDA-CBER-2021-5683-0009953

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009954

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009955

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential
FDA-CBER-2021-5683-0009956
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential

FDA-CBER-2021-5683-0009957

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009958

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009959

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable	Initial Entry

Confidential
FDA-CBER-2021-5683-0009960
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Applicable **Lab Normal Range:** Not Applicable	

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Ident** Not Applica	Initial Entry

Confidential

FDA-CBER-2021-5683-0009961

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)			**ifier:** ble **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009962

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable	Initial Entry

Confidential

FDA-CBER-2021-5683-0009963

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Result:: Not Applicable **Not Done::** Not Applicable **Lab Normal Range:** Not Applicable	

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-08-2020 16:22:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009964

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Record Identifier::** Not Applicable **Systolic::** Not Applicable **Diastolic::** Not Applicable **Respiratory Rate in respirations/minute:** Not Applicable **Heart Rate in beats/minute:** Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009965

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-08-2020 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009966

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Record Identifier::** Not Applicable **Oxygen Saturation:** Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-08-2020 16:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009967

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-08-2020 16:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009968

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 16:26:15 (UTC-06:00) Central Time	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009969

(US & Canada)				

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0009970

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/05/2020 | **Form:** IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-08-2020 16:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009971

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 15:28:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Oct-30-2020 15:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Oct-30-2020 14:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-30-2020 14:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-29-2020 05:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 3: Closed	Response satisfies query
Oct-28-2020 10:40:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 3: Answered	correct information- completed on same day
Oct-28-2020 05:12:29 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Opened	DMW5198430; The Date of Visit at Visit COVID_B is the same as the

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090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Central Time (US & Canada)				other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-27-2020 17:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-27-2020 12:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-27-2020 12:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-27-2020 12:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/27/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-30-2020 15:28:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-30-2020 14:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ERRONEOUS VISIT	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009973

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-27-2020 12:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** COVID_B	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009974

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/27/2020	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/27/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-04-2020 11:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 2: Closed	Response satisfies query
Nov-04-2020 09:38:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-04-2020 09:38:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/26/2020	Transcription Error
Nov-03-2020 19:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 2: Opened	Per source dated 27Oct20, it is reported the subjects had sore throat reported initially on diary on 26Oct. Please review and confirm entry.

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FDA-CBER-2021-5683-0009975

Nov-03-2020 18:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Melody Smart (pfe.smartm05)	Query 1: Closed	Response satisfies query
Oct-31-2020 17:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Vivian Carmichael (pfe.carmiv)	Query 1: Opened	Per progress note, subject reported med hx of seasonal allergies, symptoms starting 26Oct2020, however, AE log has start date of 27Oct2020. Please confirm and update accordingly.
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/27/2020	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/26/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 16:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Closed	Response satisfies query
Dec-08-2020 16:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-08-2020 16:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO Date of Last Symptom Resolved: Oct/29/2020	New Information

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009976

Dec-08-2020 13:11:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Dec-08-2020 08:53:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephen Paolini (pfe.paolis01)	Query 1: Candidate	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009977

Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.b

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FDA-CBER-2021-5683-0009978
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009979

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:**	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009980

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009981

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Symptoms:** CHILLS	Transcription Error

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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(US & Canada)		(pfe.lmartinez1)	**Symptom Present:**	
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** CHILLS **Symptom Present:** NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN	Initial Entry

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FDA-CBER-2021-5683-0009983

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Symptom Present:	
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN **Symptom Present:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009984

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW LOSS OF TAS TE OR SMELL **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW LOSS OF TAS TE OR SMELL **Symptom Present:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Symptoms:** NEW LOSS OF TAS	Initial Entry

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FDA-CBER-2021-5683-0009985

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.lmartinez1)	TE OR SMELL **Symptom Present:** Not Applicable	
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW LOSS OF TAS TE OR SMELL **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW LOSS OF TAS TE OR SMELL **Symptom Present:** NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.g

Date	Location	User	Value	Reason

Confidential
FDA-CBER-2021-5683-0009986
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** YES	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** NEW OR INCREASED SORE THROAT **Symptom Present:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009987

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Symptoms:** DIARRHEA	Transcription Error

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009988

(US & Canada)		(pfe.lmartinez1)	**Symptom Present:**	
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:**	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009989

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 15:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 14:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009990

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Assay Code and Description:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009991

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009992

Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-30-2020 15:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 15:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-27-2020 12:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009993

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 15:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry
Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Initial Entry
Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:33:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 15:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry
Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Initial Entry
Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:33:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009994

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-30-2020 15:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:33:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-29-2020 05:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Closed	Response satisfies query
Oct-28-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Oct-28-2020 03:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Reissued:Opened	Thanks for confirming. If sample was collected, kindly update YES here and update date of collection, also update barcode on SAMPLE ID. Thank you.
Oct-27-2020 12:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	swab was collect in office
Oct-27-2020 12:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-27-2020 12:50:09	ACV0PFEINFP6000	Yvette Davila	**Data Entry:**	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0009995

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)	NO	

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-30-2020 15:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** swab collected on site	Initial Entry
Oct-30-2020 15:27:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-29-2020 05:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Closed	no issue present in invalid report
Oct-28-2020 10:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	note added
Oct-28-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Oct-28-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	**Data Entry:** swab collected in office	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009996

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 15:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry
Oct-30-2020 14:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Oct-27-2020 17:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 15:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry
Oct-30-2020 14:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Oct-27-2020 17:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 15:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-30-2020 15:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 15:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection:	Initial Entry

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090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Oct/27/2020	
Oct-30-2020 14:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 17:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 17:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 17:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 15:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR98WB	Transcription Error
Oct-30-2020 14:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:**	Transcription Error
Oct-27-2020 17:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** **Sample ID:** BR98WB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 15:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR98WB	Transcription Error
Oct-30-2020 14:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 17:11:03 (UTC-06:00) Central Time	ACV0PFEINFP6000	Gabriela Obeidat	**Data Entry:** BR98WB	Initial Entry

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FDA-CBER-2021-5683-0009998
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

(US & Canada)		(pfe.gobeidat)		

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0009999

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** Not Done	Initial Entry
Oct-30-2020 14:35:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason

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FDA-CBER-2021-5683-0010000

Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:35:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:** Not Done	Initial Entry
Oct-30-2020 14:35:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitione** EMERGENC	Initial Entry

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(US & Canada)			**r:** Y ROOM **Occurrence of Visit s or Contacts:** NO	

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:35:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN	Initial Entry

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			Occurrence of Visits or Contacts:	
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** Not Done	Initial Entry
Oct-30-2020 14:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** NO	Initial Entry

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FDA-CBER-2021-5683-0010003

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** URGENT CARE	Initial Entry

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			Occurrence of Visits or Contacts: Not Done	
Oct-30-2020 14:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:** NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.e

Date	Location	User	Value	Reason

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FDA-CBER-2021-5683-0010005

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:** Not Done	Initial Entry
Oct-30-2020 14:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** TELEPHONE CONSULTATION **Occurrence of Visits or Contacts:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010006

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:35:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	Lizatte Martinez	**Data Entry:** **Type of Practitioner:** OTHE	Initial Entry

Confidential

FDA-CBER-2021-5683-0010007

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.lmartinez1)	R **Occurrence of Visits or Contacts:** Not Done	
Oct-30-2020 14:35:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Type of Practitioner:** OTHER **Occurrence of Visits or Contacts:** NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:35:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason

Confidential
FDA-CBER-2021-5683-0010008

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-04-2020 10:50:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Closed	Response satisfies query
Nov-04-2020 09:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	please note visit was thought to be entered in error initially, upon further review the visit was entered correctly therefore data is correct as is
Nov-03-2020 10:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Opened	DM: Per comment "visit entered in error", please verify and confirm if this visit is entered in error or not. If yes, please tick the radio button to indicate that the visit entry is erroneous. Thank you.
Oct-30-2020 15:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 15:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Initial Entry
Oct-30-2020 14:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Done	Initial Entry
Oct-30-2020 14:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010009

Header Text: c4591001	
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020	**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Oct-2020 15:59	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-27-2020 12:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010010

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 12:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010011

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-30-2020 15:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry
Oct-30-2020 14:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Oct-27-2020 12:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-30-2020 15:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Oct-30-2020 14:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-30-2020 15:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** 1	Initial Entry
Oct-30-2020 14:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-27-2020 12:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010012

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 12:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010013

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010014

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010015

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** **Sponsor-Defined Identifie** Not Don	Initial Entry

Confidential
FDA-CBER-2021-5683-0010016
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.ydavila)	**r:** e **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010017

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010018

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010019

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** **Sponsor-Defined Identifie** Not Don	Initial Entry

Confidential
FDA-CBER-2021-5683-0010020
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.ydavila)	**r:** e **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010021

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010022

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010023

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010024

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010025

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** **Sponsor-Defined Identifie** Not Don	Initial Entry

Confidential
FDA-CBER-2021-5683-0010026
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.ydavila)	**r:** e **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010027

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010028

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010029

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** **Sponsor-Defined Identifie** Not Don	Initial Entry

Confidential
FDA-CBER-2021-5683-0010030
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.ydavila)	**r:** e **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010031

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.g

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010032

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done **Result::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010033

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Not Done:: Not Done **Lab Normal Range:** Not Done	

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** **Sponsor-Defined Identifie** Not Don	Initial Entry

Confidential
FDA-CBER-2021-5683-0010034
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

(US & Canada)		(pfe.ydavila)	**r:** e **Test::** Not Done **Result::** Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010035

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Done **Test::** Not Done	Initial Entry

Confidential

FDA-CBER-2021-5683-0010036

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

			Result:: Not Done **Not Done::** Not Done **Lab Normal Range:** Not Done	

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010037

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** Not Done **Systolic::** Not Done **Diastolic::** Not Done **Respiratory Rate in respirations/minute:** Not Done **Heart Rate in beats/minute:** Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010038

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-27-2020 12:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010039

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** Not Done **Oxygen Saturation:** Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-27-2020 12:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010040

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-27-2020 12:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010041

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 12:53:43 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010042

Header Text: c4591001				
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020		**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History		
Form Version: 06-Jul-2020 21:55		**Form Status:** Data Complete, Frozen, Verified		
Site No: 1096		**Site Name:** (1096) Ventavia Research Group		
Subject No: 10961278		**Subject Initials:** ---		
Generated By: pfe.levissc		**Generated Time (GMT):** 29-Mar-2021 10:39		
(US & Canada)		(pfe.ydavila)		

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010043

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/27/2020 | **Form:** IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Done	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010044

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/02/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-02-2020 12:51:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Nov/2/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-02-2020 12:51:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COVID_A1	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010045

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/02/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Nov-02-2020 12:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 12:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-03-2020 09:38:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 02:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-02-2020 12:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-02-2020 12:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Nov/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 09:38:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSJ5SW	Initial Entry

Confidential

FDA-CBER-2021-5683-0010046

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/02/2020 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 09:38:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSJ5SW	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-03-2020 09:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSJ5SX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 09:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSJ5SX	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 09:38:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR98YY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 09:38:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BR98YY	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010047

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Dec/01/2020 | **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-01-2020 14:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Dec/1/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-01-2020 14:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COVID_B1	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010048

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Dec/01/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Dec-01-2020 17:06:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 17:06:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-01-2020 17:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 17:06:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-01-2020 17:06:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Dec/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 17:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSJ5ZJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 17:06:59	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BSJ5ZJ	

5.b

Date	Location	User	Value	Reason
Dec-01-2020 17:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSJ5ZK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 17:07:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSJ5ZK	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-01-2020 17:07:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR8568	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 17:07:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BR8568	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010050

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 12:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010051

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 - Unscheduled Visit on Oct/27/2020

Form: DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-02-2020 19:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (pfe.weavee01)	Query 1: Closed	no assessments are entered.
Nov-02-2020 17:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 1: Answered	Changed data per query
Nov-02-2020 08:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Opened	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-30-2020 15:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-30-2020 14:29:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Oct/27/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-30-2020 15:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ERRONEOUS VISIT	Initial Entry

3. COVID-19 Repeat Swab:

Date	Location	User	Value	Reason
Nov-11-2020 12:50:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe nedrickc)	Query 1: Closed	Response satisfies query
Nov-11-2020 10:08:43	ACV0PFEINFP6000	Lizatte	**Data Entry:**	Initial Entry

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FDA-CBER-2021-5683-0010052

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 - Unscheduled Visit on Oct/27/2020

Form: DATE OF VISIT - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		Martinez (pfe.lmartinez1)	Not Applicable	
Nov-11-2020 10:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	Changed data per query
Nov-10-2020 11:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Reissued:Opened	page unfrozen please update
Nov-10-2020 10:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	page needs to be unfrozen please
Nov-09-2020 23:47:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: As this visit initiated in error, update this item as Not done or else clarify. Thank you.
Oct-30-2020 15:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-30-2020 14:29:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** COVID_AR1	Initial Entry

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FDA-CBER-2021-5683-0010053

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB 1 - Unscheduled Visit on Oct/27/2020

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 15:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Transcription Error
Oct-30-2020 14:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 15:32:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-30-2020 14:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry
Oct-30-2020 15:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-30-2020 14:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 14:29:32 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010054

(US & Canada)				barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 14:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** YES Date of Collection: Oct/27/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-30-2020 15:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 15:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:**	Transcription Error
Oct-30-2020 14:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR98WB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 15:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:**	Transcription Error
Oct-30-2020 14:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR98WB	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010055

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010056

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010057

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	Form Created	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010058

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - Audit Trail
Form Version: 22-Apr-2020 21:02
Form Status:
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	Form Created	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010059

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Oct-27-2020 13:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Deleted	Transcription Error
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010060

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sialadenitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/13/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 12:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date Time: Sep/16/2020 09:00	Transcription Error
Oct-13-2020 11:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-12-2020 20:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	ongoing

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Oct-12-2020 13:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please determine if this Adverse Event is still ONGOING. Please update or clarify.
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-28-2020 09:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Oct-27-2020 12:59:03	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

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(UTC-06:00) Central Time (US & Canada)				
Oct-27-2020 12:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* unknown	Changed Information
Oct-27-2020 04:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 1: Reissued:Opened	DM: Per CRF, 'If not related to study treatment other' field, in the comment field 'Personal infection' is entered. Please confirm if any symptoms, AEs or other key data should be collected or MEDHX should be updated. If yes then update CRF. Else clarify.
Oct-26-2020 17:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	Original value is correct
Oct-26-2020 17:10:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Personal

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				infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[nazairl SDQ=20934]"
Sep-14-2020 17:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Personal infection	New Information
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-28-2020 09:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Sep-26-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-26-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	New Information
Sep-15-2020 11:12:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please complete this field.

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-27-2020 12:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 12:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RECOVERED/RESOLVED	New Information
Oct-27-2020 12:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Sialadenitis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-14-2020 17:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 06:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 3: Closed	Clin: Please complete the COVID Illness CRF forms with all information available.
Oct-12-2020 20:28:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	correct as is site will not complete a COVID illness visit per PI
Oct-12-2020 01:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 3: Reissued:Opened	Clin: Per protocol section 8.1., COVID-19 listed symptom SORE THROAT, should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID Illness CRF forms.
Oct-08-2020 09:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	Site does not understand this query..is this a question?

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Oct-04-2020 22:05:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 3: Reissued:Opened	Clin: Please potential COVID Illness Visit CRF forms should be completed with all information available. NASAL SWAB will not be collected.
Sep-30-2020 11:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 3: Answered	not covid related
Sep-29-2020 23:06:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 3: Reissued:Opened	Clin: Per protocol section 8.1., COVID-19 listed symptom SORE THROAT should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. If not a protocol deviation will be documented
Sep-28-2020 09:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 2: Closed	Response satisfies query
Sep-26-2020 11:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 3: Answered	PI deemed this not to be COVID related
Sep-26-2020 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 2: Answered	patient did contact site however this was not a COVID illness visit
Sep-15-2020 11:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 3: Opened	Clin: Please COVID-19 protocol listed symptom “SORE THROAT” should trigger a COVID Illness Visit irrespective of other potential diagnosis and a Nasal Swab needs to be collected ASAP.
Sep-15-2020 11:24:07 (UTC-06:00) Central Time	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 2: Opened	CLINQUERY: Please confirm if patient

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(US & Canada)				contacted the site for the event of Sore Throat and complete contact outcome form as applicable.
Sep-15-2020 11:20:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Need to check with Kathy
Sep-15-2020 11:19:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please confirm if patient contacted the site for the event of Sore Throat and complete contact outcome form as applicable.
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sore throat	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/13/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO End Date Time: Sep/14/2020 17:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-28-2020 09:01:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Sep-26-2020 11:10:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-26-2020 11:10:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NO	Initial Entry
Sep-15-2020 11:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please complete this field.

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Personal infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-14-2020 17:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-28-2020 11:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Closed	Response satisfies query
Sep-26-2020 11:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-26-2020 11:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Right swollen lymph node under ja w	New Information
Sep-15-2020 14:29:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Opened	GPD Clin: Please can you update the verbatim term to include location of right swollen lymph node. Thanks
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Right swollen lymph node	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Sep/13/2020 02:00	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date Time: Sep/16/2020 09:00	New Information
Oct-13-2020 11:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-12-2020 20:28:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	ongoing
Oct-12-2020 13:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Please determine if this Adverse Event is still ONGOING. Please update or clarify.
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-28-2020 09:12:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Oct-27-2020 13:16:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-27-2020 13:16:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* unknown	Changed Information
Oct-27-2020 04:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 1: Reissued:Opened	DM: Per CRF, 'If not related to study treatment other' field, in the comment field 'Personal infection' is entered. Please confirm if any symptoms, AEs or other key data should be collected or MEDHX should be updated. If

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				yes then update CRF. Else clarify.
Oct-26-2020 18:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	Original value is correct
Oct-26-2020 18:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Personal infection]. Any symptoms, AEs or other key data should be collected on the adverse event page. Please review and update as necessary. "[survea03 SDQ=20936]"
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* Personal infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010074

Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-27-2020 13:17:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 13:17:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RECOVERED/RESOLVED	New Information
Oct-27-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Right swollen lymph node under jaw: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-14-2020 17:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010075

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-31-2020 13:49:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Oct-28-2020 11:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	per protocol PI discretion and he did not think covid illness visit was needed. correct as is. if else please clarify.
Oct-27-2020 21:28:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected.
Oct-26-2020 11:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rocio Gutierrez (pfe.rgutierrez)	Query 1: Answered	PER PI NO COVID ILLNESS VISIT NEEDED.
Oct-25-2020 17:16:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Please complete the potential COVID-19 Illness

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				Visit CRF forms with all information available.
Oct-23-2020 19:32:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	updated
Oct-23-2020 08:42:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Per protocol section 8.13., COVID-19 listed symptom NEW or INCREASED MUSCLE PAIN should have triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance and should be captured on the CRF SOD form only.
Oct-22-2020 21:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-22-2020 21:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Generalized muscle aches due to ex ercise	Transcription Error
Oct-15-2020 20:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Per protocol sec 8.1., COVID-19 symptom NEW or INCREASED MUSCLE PAIN, start date d post Dose , should please trigger a potential COVID Illness Visit irrespective of perceived etiology or clinical significance and a nasal swab collected ASAP.
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Generalized muscle aches	Initial Entry

4. Start Date Time:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Sep/22/2020 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 13:09:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 2: Closed	Response satisfies query
Dec-02-2020 12:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Query 2: Answered	will update at next scheduled visit
Nov-30-2020 10:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 2: Opened	CLINQUERY: Please determine if this Adverse Event is still ONGOING as it has been 69 days since Onset Date. Please update or confirm.
Oct-13-2020 11:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Oct-12-2020 20:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	Query 1: Answered	ongoing
Oct-12-2020 13:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Please determine if this Adverse Event is still ONGOING. Please update or clarify.
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

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If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 08:54:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Closed	Response satisfies query
Oct-23-2020 19:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 19:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* due to exercise	Transcription Error
Oct-23-2020 08:48:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe kolbek01)	Query 1: Opened	CLINQUERY: Per the updated AE Term, please determine if the Relationship of RELATED is appropriate or if this should be updated to OTHER - Due to

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				Exercise. Please update or clarify accordingly.
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe rsaenz)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-08-2020 15:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

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090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** sore throat	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/3/2020 11:01	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date Time: Oct/6/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** 1	Initial Entry

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***** THIS REPEATING FORM HAS BEEN DELETED *****

(US & Canada)		(pfe.ydavila)		

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 13:06:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason

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FDA-CBER-2021-5683-0010082
090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Deleted, Frozen, Verified
Site No: 1096
Site Name: (1096) Ventavia Research Group
Subject No: 10961278
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 10:39

***** THIS REPEATING FORM HAS BEEN DELETED *****

Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-27-2020 13:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 13:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RECOVERED/RESOLVED	Transcription Error
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE sore throat: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 13:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010083

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Date	Location	User	Value	Reason
Oct-27-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	Form Created	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010084

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-27-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-27-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Oct/13/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010085

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 13:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/11/2021	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010086

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-14-2021 13:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010087

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-14-2021 13:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Jan/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-14-2021 13:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010088

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Jan-14-2021 13:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010089

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-14-2021 13:27:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010090

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 10:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/18/2021	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010091

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-19-2021 10:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/18/2021	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010092

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-19-2021 10:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/18/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-19-2021 10:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-19-2021 10:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010093

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 13:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 13:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 13:28:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 13:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 13:28:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR85D8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:28:49	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0010094

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BR85D8	

5.b

Date	Location	User	Value	Reason
Jan-19-2021 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH498	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH498	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-19-2021 13:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSH499	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSH499	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010095

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 13:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 13:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 13:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 13:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 13:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BR85DN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:29:50	ACV0PFEINFP6000	Yvette	**Data Entry:**	Initial Entry

Confidential

FDA-CBER-2021-5683-0010096

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Header Text: c4591001	
Visit: V101_VAX3	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961278	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		Davila (pfe.ydavila)	BR85DN	

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010097

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Jan/18/2021 11:03	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** LEFT	Initial Entry

7. Route:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010098

Header Text: c4591001
Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-19-2021 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010099

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 10:34:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/9/2021	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010100

Header Text: c4591001

Visit: V102_VAX4 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 10:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 10:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 14:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 10:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 10:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZNKK	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010101

Header Text: c4591001

Visit: V102_VAX4 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZNKK	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010102

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Feb/9/2021 10:38	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** LEFT	Initial Entry

7. Route:

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010103

Header Text: c4591001
Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096 **Site Name:** (1096) Ventavia Research Group
Subject No: 10961278 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-09-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential
FDA-CBER-2021-5683-0010104

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 18:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Mar/11/2021	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010105

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Contact Type:

Date	Location	User	Value	Reason
Mar-11-2021 18:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-11-2021 18:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** YES Date of Contact: Mar/11/2021	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010106

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961278

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-11-2021 18:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Mar/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-11-2021 18:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-11-2021 18:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010107

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 12:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Sep-08-2020 22:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Sep-08-2020 22:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-29-2020 12:00:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/27/2020	Transcription Error
Oct-27-2020 12:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/27/2020	Initial Entry
Sep-08-2020 22:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/5/2020	Initial Entry
Sep-08-2020 22:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/8/2020	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

Confidential

FDA-CBER-2021-5683-0010108

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961278 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-02-2020 17:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gabriela Obeidat (pfe.gobeidat)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae3093\Final\Final On: 01-Apr-2021 04:10 (GMT)

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FDA-CBER-2021-5683-0010109

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 15-Sep-2020 21:55	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010110

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/17/2020

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010111

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 15-Sep-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Demography		
1.	Subject ID	[10961355]
2.	Birth Date:	(b) (6)/1960
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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FDA-CBER-2021-5683-0010112

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0010113

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 15-Sep-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

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FDA-CBER-2021-5683-0010114

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 15-Sep-2020 21:52 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/17/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010115

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Abnormal uterine bleeding]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hysterectomy (complete)]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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FDA-CBER-2021-5683-0010116

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Lower back injury]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

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FDA-CBER-2021-5683-0010117

1.g

Line/MH Number:	[7]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Back muscle spasms]
Start Date:	UNK/UNK/2003
Ongoing:	YES

1.h

Line/MH Number:	[8]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Breast augmentation]
Start Date:	UNK/UNK/2008
Ongoing:	NO End Date: UNK/UNK/2008

1.i

Line/MH Number:	[9]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Cesarean section]
Start Date:	May/30/1980
Ongoing:	NO End Date: May/30/1980

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010118

1.j

Line/MH Number:	[10]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obesity]
Start Date:	UNK/UNK/2010
Ongoing:	YES

1.k

Line/MH Number:	[11]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Post menopausal]
Start Date:	UNK/UNK/2008
Ongoing:	YES

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010119

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** HIV STATUS
Form Version: 15-Sep-2020 21:57	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

HIV Status		
1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE

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FDA-CBER-2021-5683-0010120

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/17/2020
2.	Weight:	[214.06]
3.	Unit:	LB
4.	Height:	[62.0]
5.	Unit:	in
6.	Body Mass Index:	[39.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010121

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 15-Sep-2020 21:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010122

Header Text: c4591001

Visit: V1_DAY1_VAX1_L **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Sep/17/2020
2.	Randomization Number:	[260833]
3.	Randomization Group:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010123

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNVTL0]
5.b	Sample ID	[BNVTL1]
5.c	Sample ID	[BNZP1F]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010124

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BNZP1K]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010125

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/17/2020 16:34
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010126

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010127

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010128

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vital Signs

1.	Date:	Oct/8/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[98.1]
Unit:	F
Temperature Location:	ORAL CAVITY

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010129

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 15-Sep-2020 21:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Form Comments
eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010130

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR8523]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010131

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/8/2020 15:24
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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FDA-CBER-2021-5683-0010132

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Nov/12/2020
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0010133

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR854S]
5.b	Sample ID	[BSJ5WF]
5.c	Sample ID	[BSJ5WG]

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FDA-CBER-2021-5683-0010134

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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FDA-CBER-2021-5683-0010135

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010136

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

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FDA-CBER-2021-5683-0010137

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

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FDA-CBER-2021-5683-0010138

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

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FDA-CBER-2021-5683-0010139

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

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FDA-CBER-2021-5683-0010140

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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FDA-CBER-2021-5683-0010141

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

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FDA-CBER-2021-5683-0010142

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010143

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

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FDA-CBER-2021-5683-0010144

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

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FDA-CBER-2021-5683-0010145

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Unplanned Assessments		
1.	Assessments	

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FDA-CBER-2021-5683-0010146

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Adverse Event Report

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	

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8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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FDA-CBER-2021-5683-0010148

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010149

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010150

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	[ ]			[ ]		Repeating Pages

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010151

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010152

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010153

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Concomitant Medications

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

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FDA-CBER-2021-5683-0010154

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010155

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010156

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010157

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010158

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Nov/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010159

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010160

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010161

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010162

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010163

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

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FDA-CBER-2021-5683-0010164

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010165

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010166

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010167

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010168

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Mar/3/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010169

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010170

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010171

Header Text: c4591001

Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010172

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Informed Consent - Further Vaccination		
1.	Consent Was:	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010173

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010174

Header Text: c4591001

Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Not Started
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010175

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/12/2020

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010176

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010177

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010178

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Sep-17-2020 20:19:48 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010179

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
Form	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010180

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010181

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010182

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010183

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010184

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010185

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 15-Sep-2020 21:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010186

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010187

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 15-Sep-2020 21:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	Yvette Davila (pfe.ydavila)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010188

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010189

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
1	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010190

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010191

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010192

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010193

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010194

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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Item	Date	User	Comment
6.a	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010195

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
6.a	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010196

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

Item	Date	User	Comment
6.a	Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	Rene Saenz (pfe.rsaenz)	Not Applicable

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010197

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lizatte Martinez	N/A	Mar-03-2021 18:47:34 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Van Tran	Approved	Nov-16-2020 14:48:46 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Yvette Davila	N/A	Nov-13-2020 16:12:10 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010198

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Affidavit:
N/A

Van Tran	Approved	Nov-13-2020 14:47:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Yvette Davila	N/A	Nov-13-2020 12:30:06 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Van Tran	Approved	Nov-10-2020 14:36:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010199

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Affidavit:

By my dated signature below, I, VanTran, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010200

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:55	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-17-2020 20:17:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 08 SEP 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-17-2020 20:17:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010201

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Sep-17-2020 20:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** OBTAINED Date Written Consent Obtained Sep/17/2020	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010202

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Sep-17-2020 20:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10961355	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:17:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1960	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-17-2020 20:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010203

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Sep-17-2020 20:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-17-2020 20:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** WHITE	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010204

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 20:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/17/2020	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010205

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-17-2020 20:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-17-2020 20:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-17-2020 20:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010206

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1.a

Date	Location	User	Value	Reason
Sep-17-2020 20:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Abnormal uterine bleeding **Start Date:** UNK/UNK/2008 **Ongoing:** NO End Date: UNK/UNK/2008	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010207

Sep-17-2020 20:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Abnormal uterine ble eding	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO End Date: UNK/UNK/2008	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-17-2020 20:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010208

			Medical History Term: Hysterectomy (complete) **Start Date:** UNK/UNK/2008 **Ongoing:** NO End Date: UNK/UNK/2008	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010209

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Hysterectomy (complete)	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:22:29	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** NO	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010210

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)	End Date: UNK/UNK/2008	

1.c

Date	Location	User	Value	Reason
Sep-17-2020 20:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Hypertension **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010211

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Hypertension	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:23:55	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010212

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		

1.d

Date	Location	User	Value	Reason
Sep-17-2020 20:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** Anxiety **Start Date:** UNK/UNK/1998 **Ongoing:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010213

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Anxiety	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/1998	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:24:41	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010214

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		

1.e

Date	Location	User	Value	Reason
Sep-17-2020 20:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** Depression **Start Date:** UNK/UNK/1998 **Ongoing:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010215

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Depression	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/1998	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:13	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010216

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		

1.f

Date	Location	User	Value	Reason
Sep-17-2020 20:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** Lower back injury **Start Date:** UNK/UNK/2003 **Ongoing:** NO End Date: UNK/UNK/2003	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010217

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Lower back injury	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2003	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:25:54	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** NO	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010218

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)	End Date: UNK/UNK/2003	

1.g

Date	Location	User	Value	Reason
Sep-17-2020 20:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** Back muscle spasms **Start Date:** UNK/UNK/2003 **Ongoing:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010219

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Back muscle spasms	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2003	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:26:24	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010220

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		

1.h

Date	Location	User	Value	Reason
Sep-17-2020 20:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** Breast augmentation **Start Date:** UNK/UNK/2008 **Ongoing:** NO End Date: UNK/UNK/2008	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010221

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Breast augmentation	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:27:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:27:02	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** NO	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010222

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)	End Date: UNK/UNK/2008	

1.i

Date	Location	User	Value	Reason
Sep-17-2020 20:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** Cesarean section **Start Date:** May/30/1980 **Ongoing:** NO End Date: May/30/1980	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010223

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Cesarean section	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** May/30/1980	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:28:01	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** NO	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010224

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)	End Date: May/30/1980	

1.j

Date	Location	User	Value	Reason
Sep-17-2020 20:29:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 10 **Medical History Term:** Obesity **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010225

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Obesity	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:06	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010226

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010227

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1.k

Date	Location	User	Value	Reason
Nov-04-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** Post menopausal **Start Date:** UNK/UNK/2008 **Ongoing:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010228

1.k Line/MH Number:

Date	Location	User	Value	Reason
Nov-04-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-04-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Post menopausal	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Nov-04-2020 14:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** UNK/UNK/2008	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Nov-04-2020 14:08:58	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010229

(UTC-06:00) Central Time (US & Canada)				

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010230

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** HIV STATUS - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:57 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Sep-17-2020 20:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** The subject is NOT k nown to be HIV POS ITIVE	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010231

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:56	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 214.06	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010232

Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 62.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 39.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 97.8	Initial Entry

Confidential
FDA-CBER-2021-5683-0010233
090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

			Temperature Unit: F **Temperature Location ::** ORAL CAVITY	

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** F	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010234

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:56	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 20:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010235

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010236

Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010237

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-17-2020 20:30:33	ACV0PFEINFP6000	Yvette Davila	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010238

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(pfe.ydavila)		

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010239

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-17-2020 20:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-17-2020 20:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** 260833	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010240

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 14:03:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Sep-21-2020 16:42:27 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010241

Central Time (US & Canada)				
Sep-21-2020 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-21-2020 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/17/2020	Initial Entry
Sep-21-2020 10:31:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Please scan at least 5 sample IDs (including 2 retainer samples) for Immunogenicity collection below. Otherwise, provide

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010242

				comment in Question 4 as to why was sample not collected according to protocol.

5.a

Date	Location	User	Value	Reason
Sep-21-2020 16:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID :** BNVTL 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 16:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNVTL0	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 16:42:36 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID :** BNVTL 1	Initial Entry

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FDA-CBER-2021-5683-0010243
090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

& Canada)				

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 16:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNVTL1	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 16:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BNZP1F	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 16:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZP1F	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010244

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 13:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 13:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 14:03:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Closed	Response satisfies query
Sep-21-2020 13:34:46 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010245

Central Time (US & Canada)				
Sep-21-2020 13:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 13:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-21-2020 13:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Sep/17/2020	Initial Entry
Sep-21-2020 10:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Karin Kolbe (pfe.kolbek01)	Query 1: Opened	CLINQUERY: Per Protocol, a NASAL SWAB should have been taken. If this was done, please enter the data. Otherwise, provide clarification.

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010246

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Sep-21-2020 13:34:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID :** BNZP1K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 13:34:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BNZP1K	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010247

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010248

Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Sep/17/2020 16:34	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential
FDA-CBER-2021-5683-0010249

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-17-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010250

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-17-2020 20:34:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010251

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 17:58:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/8/2020	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010252

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-09-2020 17:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-09-2020 17:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 98.1 **Temperature Unit:** F **Temperature Location::** ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-09-2020 17:59:57 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** 1	Initial Entry

Confidential

FDA-CBER-2021-5683-0010253

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

& Canada)				

2.a Temperature:

Date	Location	User	Value	Reason
Oct-09-2020 17:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-09-2020 17:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-09-2020 17:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** ORAL CAVITY	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010254

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010255

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010256

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-09-2020 18:00:28	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Not Applicable	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010257

(UTC-06:00) Central Time (US & Canada)				

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010258

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 18:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 18:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 19:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 18:00:46 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010259

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 18:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 19:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** **Sample ID:** BR8523	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 19:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** BR8523	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010260

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010261

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** Oct/8/2020 15:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010262

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-09-2020 18:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rene Saenz (pfe.rsaenz)	**Data Entry:** YES	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010263

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Nov-13-2020 12:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Nov/12/2020	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010264

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Nov-13-2020 12:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-13-2020 12:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-13-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-13-2020 12:30:17 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010265

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-13-2020 12:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** YES Date of Collection: Nov/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID :** BR854S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BR854S	Initial Entry

5.b

Date	Location	User	Value	Reason

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010266

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

Nov-13-2020 12:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSJ5WF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 12:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSJ5WF	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-13-2020 12:31:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** **Sample ID:** BSJ5WG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 12:31:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** BSJ5WG	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010267

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1096 **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-13-2020 16:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** Nov/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-13-2020 16:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-13-2020 16:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Yvette Davila (pfe.ydavila)	**Data Entry:** COMPLETED	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010268

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 18:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Mar/3/2021	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

Confidential

FDA-CBER-2021-5683-0010269

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 | **Form Status:** Data Complete, Frozen

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-03-2021 18:48:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 18:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-03-2021 18:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirme	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010270

			d to have received only placebo at Vaccination 1/2	

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010271

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1096	**Site Name:** (1096) Ventavia Research Group
Subject No: 10961355	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 10:39

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-03-2021 18:48:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Mar/3/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-03-2021 18:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010272

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1096 | **Site Name:** (1096) Ventavia Research Group

Subject No: 10961355 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 10:39

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1. Subject Status

Date	Location	User	Value	Reason
Nov-13-2020 16:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Sep-17-2020 20:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Sep-17-2020 20:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-13-2020 16:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Nov/12/2020	Initial Entry
Sep-17-2020 20:34:11	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/17/2020	Initial Entry

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FDA-CBER-2021-5683-0010273

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

(UTC-06:00) Central Time (US & Canada)				
Sep-17-2020 20:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/17/2020	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010274

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1096

Site Name: (1096) Ventavia Research Group

Subject No: 10961355

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:39

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 14:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lizatte Martinez (pfe.lmartinez1)	**Data Entry:** Click Here to Enable	Initial Entry

090177e196ae3090\Final\Final On: 01-Apr-2021 04:09 (GMT)

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FDA-CBER-2021-5683-0010275